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#21 Brief of Appeal
7-23-03

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP APPEAL BRIEF - PATENTS, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE INDICATED BELOW

BY: _____ DATE: 7/8/2003

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of Akers et al.	: Group Art Unit: 3626
Appln. No.:	09/851,745	: Examiner: R. Morgan
Filed:	May 9, 2001	:
For:	SYSTEM AND METHOD FOR ELECTRONIC MEDICAL FILE MANAGEMENT	: Attorney Docket : No. 015351-0001 (B69465)

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APPELLANT'S BRIEF (37 C.F.R. § 1.192)

This brief is in furtherance of the Notice of Appeal, filed in this case on April 2, 2003 and received on April 8, 2003.

The fees required under § 1.17 are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate. (37 C.F.R. § 1.192(a)).

This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. § 1.192(c)).

I. REAL PARTY OF INTEREST

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The final page of this brief bears the practitioner's signature.

I. REAL PARTY OF INTEREST (37 C.F.R. § 1.192(c)(1))

The real party in interest in this appeal is Healthcare Vision, Inc.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 1.192(c)(2))

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS (37 C.F.R. § 1.192(c)(3))

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: 35 claims. (Claims 1-35)

Claims currently pending in the application: 35 pending claims

B. STATUS OF ALL THE CLAIMS

1. Claims cancelled: NONE
2. Claims withdrawn from consideration but not cancelled: NONE
3. Claims pending: 1-35
4. Claims allowed: NONE
5. Claims rejected: 1-35

C. CLAIMS ON APPEAL

The claims on appeal are: 1-35

IV. STATUS OF AMENDMENTS (37 C.F.R. § 1.192(c)(4))

A Request for Reconsideration was filed on March 3, 2003. The Request for Reconsideration was not entered by the Examiner, as stated in paragraph 1 of the Examiner's Advisory Action dated March 21, 2003 (paper no. 18). The claims presently pending are those submitted October 9, 2002, in response to the non-final Office Action dated September 12, 2002 (paper no. 12).

V. SUMMARY OF THE INVENTION (37 C.F.R. § 1.192(c)(5))

The following summary is provided without any intention to limit the scope of the claims. The subject matter of claims 1-35 is summarized below.

Claim 1 includes a system is provided for transferring electronic medical files. A record server has a medical record data file, the medical record data file has medical record data. A record client coupled to the record server receives the medical record data file. The medical record data is "encapsulated" to prevent modification of the medical record data. Page 15, lines 8-24 lists examples of encapsulation. Claim 10 provides a related method that includes encapsulating medical record data to prevent it from being modified.

Claim 16 includes a system for distributing medical supplies in which a record server receives package data. A record client coupled to the record server receives the package data from the record server and verification data. The record server receives the verification data from the record client and correlates the verification data to the package data. An example of a record client and record server that use package data and verification data in this manner is provided at paragraphs 0090 through 0095 of the specification and Figure 8. Claim 20 provides a related method that includes authorizing release of the package if stored package data, such as that from the record server, matches received package data, such as verification data or other suitable data from the record client.

Claim 23 includes a system for transferring electronic medical files that includes a record server having an encapsulated medical record data file, the encapsulated medical record data file having medical record data that can be viewed but which cannot be modified. A record client is coupled to the record server and receives the encapsulated medical record data file. A sync system verifies that the record client has received sync data before transferring the encapsulated medical record data file. The record server further comprises a tracking system that updates a

tracking record when the encapsulated medical record data file is transferred, and the record client further comprises a tracking system that updates a tracking record when the encapsulated medical record data file is accessed. The record client further comprises a detail encapsulation system that receives comment data, encapsulates the comment data to prevent it from being modified, and stores the encapsulated comment data as part of the encapsulated medical record data file. The record client operates in unattended mode such that the encapsulated medical record data file can be received without an operator present.

Claim 24 includes a method for transferring electronic medical data that includes determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system. Electronic medical data is transferred to the patient file if it is determined that it exists, and the patient file is created with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system. The electronic medical data is then transferred to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system.

Claim 27 includes a method for transferring electronic medical record data that includes extracting an excerpt of the electronic medical record data from an electronic medical record data file at a first location. The excerpt is transmitted to a remote location, and comment data associated with the excerpt is received. The comment data is transmitted to the first location.

Claim 29 includes a method for transferring electronic medical record data that comprises encapsulating an electronic medical record file so as to allow it to be viewed and to prevent it from being modified. The encapsulated electronic medical record file is then encrypted. The encrypted encapsulated electronic medical record file is then transmitted to a remote location. The encrypted encapsulated electronic medical record file is then decrypted at the remote location, and a user-readable display is generated using the encapsulated electronic medical record file.

Narrower embodiments of the invention are described below.

Claim 2 depends from claim 1 and provides that the record server further comprises a sync system verifying that the record client has received a sync file before transferring the medical record data file.

Claim 3 depends from claim 1 and provides that the record server further comprises a tracking system updating a tracking record when the medical record data file is transferred.

Claim 4 depends from claim 1 and provides that the record client further comprises a tracking system updating a tracking record when the medical record data file is accessed.

Claim 5 depends from claim 1 and provides that the record client further comprises a remote data system, the remote data system generating medical record data, wherein the record client encapsulates the medical record data to prevent it from being modified.

Claim 6 depends from claim 1 and provides that the record client system further comprises a detail encapsulation system receiving comment data and encapsulating the comment data to prevent it from being modified.

Claim 7 depends from claim 1 and provides that the record server further comprises a record storage system, the record storage system storing each version of the medical record data file received by the record server.

Claim 8 depends from claim 1 and provides that the record server further comprises an excerpt transfer system, the excerpt transfer system receiving medical record excerpt data and transferring it to a predetermined recipient.

Claim 9 depends from claim 1 and provides a notification system transferring notification data to a party regarding the availability of medical record data.

Claim 11 depends from claim 10 and provides that transferring the medical record data file to the remote location further comprises transferring a sync file to the remote location.

Claim 12 depends from claim 10 and provides that assembling the medical record data into the medical record data file further comprises storing a tracking record with the medical record data file.

Claim 13 depends from claim 10 and provides generating notification data at the remote location.

Claim 14 depends from claim 10 and provides accessing the medical record data file at the remote location; and updating a tracking record to show that the medical record data file has been accessed at the remote location.

Claim 15 depends from claim 10 and provides receiving medical record data at the remote location; encapsulating the medical record data to prevent the medical record data from being modified; and updating the medical record data file to include the medical record data.

Claim 17 depends from claim 16 and provides an inventory tracking system receiving the verification data and incrementing order data.

Claim 18 depends from claim 16 and provides a record encapsulation system receiving the verification data and encapsulating the verification data in a medical record data file.

Claim 19 depends from claim 16 and provides a remote data system generating counseling data and transmitting the counseling data to the record server.

Claim 21 depends from claim 20 and provides that receiving the package data from the remote site further comprises counseling a patient if the patient has not received the medical supplies before; and generating counseling data.

Claim 22 depends from claim 20 and provides incrementing order data after the package is released.

Claim 25 depends from claim 24 and provides that the remote system operates in an unattended mode that allows the electronic medical data to be transferred without operator input.

Claim 26 depends from claim 25 and provides that the remote system receives electronic medical data for two or more users in unattended mode, and each user must enter a user-specific access ID to access the electronic medical data for that user.

Claim 28 depends from claim 27 and provides that extracting an excerpt of the electronic medical record data from the electronic medical record data file comprises removing user-readable patient identifying data.

Claim 30 depends from claim 29 and provides that the electronic medical record file is an image data file.

Claim 31 depends from claim 2 and provides that the sync file is a patient file.

Claim 32 depends from claim 1 and provides that the medical record client operates in unattended mode, so as to allow the medical record data file to be received without user input.

Claim 33 depends from claim 11 and provides that transferring the sync file comprises creating a patient folder.

Claim 34 depends from claim 16 and provides that the record client further comprises a data reader that reads the verification data from the package.

Claim 35 depends from claim 16 and provides that the record client further comprises an image data capture device that generates image data, and the verification data includes the image data.

VI. ISSUES ((37 C.F.R. § 1.192(c)(6))

Whether claims 24 and 27 are unpatentable under 35 U.S.C. § 102(b) over Evans.

Whether claims 1-15, 23, 28-29, 30-31, and 33 are unpatentable under 35 USC § 103(a) over Evans in view of McGauley.

Whether claims 16, 17, 19, and 35 are unpatentable under 35 U.S.C. § 103(a) over Evans in view of Portwood.

Whether claim 18 is unpatentable under 35 U.S.C. § 103(a) over Evans and Portwood in view of McGauley.

Whether claims 25, 26, and 32 are unpatentable under 35 U.S.C. § 103(a) over Evans.

Whether claim 34 is unpatentable under 35 U.S.C. § 103(a) over Evans and Portwood in view of Chudy.

Evans – U.S. Patent No. 5,924,074

McGauley – U.S. Patent No. 5,899,998

Portwood – U.S. Patent No. 6,305,377

Chudy – U.S. Patent No. 6,370,841

VII. GROUPING OF CLAIMS ((37 C.F.R. § 1.192(c)(6))

The following claim groupings are considered as standing or falling separately:

(a) Claims 24-28

(b) Claims 1-15, 23 and 29-33

(c) Claims 16-22, 34 and 35

(d) Claims 2, 11, 23, 31 and 33

The reasons for separate patentability are set forth below.

VIII. ARGUMENTS ((37 C.F.R. § 1.192(c)(6))
ARGUMENT: VIIIC – REJECTIONS UNDER 35 U.S.C. 102 (37 C.F.R. § 1.192(c)(8)(iii))

1. Background to Presently Claimed Invention

The presently claimed invention provides a method for electronic medical file management that resolves problems that exist with prior art systems, mainly in the area of data security. In one exemplary embodiment, it is first determined whether a patient file having a predetermined patient data structure exists for a patient on a remote system. Electronic medical data is transferred to the patient file if it is determined that it exists, and the patient file is created with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system. The electronic medical data is then transferred to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system. In another exemplary embodiment, an excerpt of the electronic medical record data is extracted from an electronic medical record data file at a first location. The excerpt is transmitted to a remote location, and comment data associated with the excerpt is received. The comment data is transmitted to the first location.

2. Evans

Evans discloses an electronic medical records system with limited data security. Some of the features described in the patent are as follows:

(1) A patient data repository 102 that stores all of the patient data in a single location. See column 5, line 1 through column 5, line 20 of Evans.

(2) Point of care systems 100 that obtain a patient record 111 from the patient data repository 102.

(3) A new form window with edit functionality. See Figure 6.

(4) An annotate window with edit functionality. See Figure 7.

(5) A viewer window displaying an image of patient data with edit functionality. See Figure 8.

(6) A diagnosis module and a procedure module with "remove" and "clear" functionality. See Figure 20.

(7) A graphical user interface for a medication manager with "edit," "clear," and "remove all" functionality. See Figure 21.

The Evans patent describes many other features which are not relevant to the present invention.

3. Patentability of claims 24 through 28

Electronic medical record data can be inadvertently misused by importing the patient record of the wrong patient, such as where two patients have the same name, where the patient's name is spelled incorrectly, where a social security number is incorrectly entered, or in other circumstances. In one exemplary embodiment, the method of claims 24 through 28 prevents such errors by determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system and creating the patient file with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system. The Examiner's construction of claims 24 through 28 would allow such errors to occur, and thus reads limitations out of the claims. Federal Circuit precedent prohibits construing claims in a manner that reads elements out of the claim. *Texas Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993).

Claim 24 includes "determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system, transferring the electronic medical data to the patient file if it is determined that it exists, creating the patient file with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system; and transferring the electronic medical data to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system." The Examiner construed these elements to be that disclosed at column 8, lines 21-60 and Figures 1 and 13 of Evans. Claim construction is reviewed *de novo* by the Board of Patent Appeals and Interferences. Further, it is axiomatic that "that which anticipates if earlier infringes if later." Thus, it needs to be determined *de novo* whether the method disclosed in Evans would infringe the proper construction of claim 24.

The cited sections of Evans disclose a patient data repository 102 that has patient files having a predetermined data structure. *See* Figure 13 of Evans. When a remote system such as that disclosed at column 2, lines 29-55 of Evans requires a patient record, it "obtains the patient record 111 from the patient data repository 102. . . . At the conclusion of the patient's visit, the EMR system files the patient's record 119 in the patient data repository 102." Evans, col. 5,

lines 33-55. Figure 13 shows the "structure of a patient record." Evans, col. 4, lines 8-9. This structure is only present at the remote location when patient record 111 is obtained from patient data repository 102 when it is required by the remote system, such as prior to a patient appointment. It is then returned as patient record 119 to patient data repository 102 after the appointment, in order to maintain record integrity. Thus, the system of Evans disclosed in the sections cited by the Examiner fails to disclose "determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system; transferring the electronic medical data to the patient file if it is determined that it exists; creating the patient file with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system; and transferring the electronic medical data to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system." Instead, the entire patient record 111 is obtained from the patient data repository 102 at the remote system each time it is needed, and is returned to the patient data repository 102 as patient record 119 when it is no longer needed. There is no step of "determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system," because the patient record 111 is transferred from the patient data repository 102 at the beginning of each session at the remote location and is returned as patient record 119 to the patient data repository 102 at the completion of the session at the remote location. There is also no "transferring the electronic medical data to the patient file if it is determined that it exists," because it never exists until patient record 111 is transferred, at which point no further transferring of data is performed. Because Evans would not infringe claim 24 as properly construed, the Examiner's construction is incorrect and should be reversed.

Claim 25 depends from claim 24 and includes the remote system operating in an unattended mode that allows the electronic medical data to be transferred without operator input. The Examiner construed this to be "merely automatically updating or transferring the data without operator input." However, this construction reads the limitation of transferring the data to the remote location without operator input out of the claim – Evans discloses that the EMR system at the remote location obtains the patient record 111, such as when an appointment is scheduled. Evans, col. 5, lines 29-32. The patient data repository 102 cannot initiate the transfer. Thus, the construction adopted by the Examiner reads out the limitation that the data is transferred to the **remote location** without operator input. Furthermore, the Examiner's

construction reads out the limitation that the remote location is operating in an unattended mode – "merely automatically updating or transferring data without operator input" does not require the remote location to be operating in any particular mode, and can be performed while the remote location is attended. Therefore, the Examiner's construction of claim 25 improperly reads limitations out of the claim and should be reversed.

Claim 26 depends from claim 25 and includes that the remote system receives electronic medical data for two or more users in unattended mode, and each user must enter a user-specific access ID to access the electronic medical data for that user. Again, the Examiner's construction (which is the same as claim 25) reads limitations out of the claim, such as the unattended mode allowing data for different users to be received and that a user-specific password can be required to access the data. "Merely automatically updating or transferring data without operator input" does not include the limitations of an unattended mode at the remote system, data being received for different users, and user-specific passwords being used to access the data received in unattended mode. As such, the Examiner's construction is incorrect and should be reversed.

The Examiner construed claim 27 to be that disclosed by column 3, lines 36-42, column 4 line 64 to column 5 line 8, and column 6, lines 31-36 of Evans, and Figure 4 of Evans. The Examiner further construed the claim as follows: "The Examiner considers the progress notes (144, Fig. 4) to be transferred from healthcare providers to another." As previously described, Evans discloses the transfer of the entire patient record 111 from the patient data repository 102 to the remote location, and return of the entire patient record 119 to the patient data repository 102 at the conclusion of the patient's visit. At column 3, lines 36-42 of Evans, transferring patient data from an external source to the electrical medical records system is disclosed. This refers to interfacing with external data sources that do not use the patient record 111 data format in the patient data repository. *See, e.g.*, Evans, col. 10, line 18 through col. 11, line 9. A communication interface 274 is used to convert "external patient data into formats recognized by the EMR system." At column 4 line 64 to column 5 line 8, the general process of receiving data from external sources is disclosed. At column 6, lines 31-36 of Evans, progress notes 144 are described as being added to the patient record 111, and not to an excerpt of that record. The entire patient record 119 (including the progress notes 144) is then returned to the patient data repository 102, such that the entire patient record 111 (and not just an excerpt) must be obtained

in order to get the progress notes. The construction adopted by the Examiner is incorrect, and therefore, the rejection should be reversed.

Claim 27, properly construed, includes "extracting an excerpt of the electronic medical record data from an electronic medical record data file at a first location; transmitting the excerpt to a remote location; receiving comment data associated with the excerpt; transmitting the comment data to the first location." Thus, the system of Evans would not infringe claim 27. The system of Evans does not extract an excerpt of the electronic medical record data from an electronic medical record data file at a first location and transmit the excerpt to a remote location, but instead transmits the entire patient record 111 to a remote location. Although data can be received from external sources, such external sources do not provide comment data in response to excerpt data. The only comment data that is received by a user of the system of Evans is transmitted with the entire patient record 111. One advantage of the claimed invention is that the entire patient record 111 does not need to be transmitted to a remote location in order to receive comment data – using the system of Evans, transmission of the entire patient record 111 to remote locations via many common handheld devices would not be possible, either due to bandwidth or memory constraints of such handheld devices and the associated communications media. As such, the Examiner's construction of claim 27 improperly reads limitations out of the claim and should be reversed.

Claim 28 depends from claim 27 and states that extracting an excerpt of the electronic medical record data from the electronic medical record data file comprises removing user-readable patient identifying data. The Examiner construes this claim as being transferring "patient data from the electronic medical records system to other healthcare providers and between external sources." Paper no. 12, page 4. However, this construction plainly reads out the limitation of "removing user-readable patient identifying data." Some of the "external sources" listed in Evans at column 3, lines 36-42 and column 4 line 64 to column 5 line 8 include physicians, hospitals, laboratories, and clinics, and some of the data includes laboratory results and prescriptions. What value are laboratory results and prescriptions to a physician or clinic if not accompanied by user-readable patient identifying information? The Examiner's construction of this claim fails to meet the requirements set forth by the Federal Circuit.

VIII. ARGUMENTS ((37 C.F.R. § 1.192(c)(6))
ARGUMENT: VIIID – REJECTIONS UNDER 35 U.S.C. 103 (37 C.F.R. § 1.192(c)(8)(iv))

1. Background to Presently Claimed Invention

In one exemplary embodiment, the presently claimed invention provides a system for transferring electronic medical files that includes a record server having a medical record data file, the medical record data file having medical record data; a record client coupled to the record server, the record client receiving the medical record data file; and wherein the medical record data is encapsulated to prevent modification of the medical record data.

In another exemplary embodiment, the presently claimed invention provides a method for transferring electronic medical files that includes encapsulating medical record data to prevent it from being modified; assembling the medical record data into a medical record data file; receiving a request to transfer the medical record data file; and transferring the medical record data file to a remote location.

In another exemplary embodiment, the presently claimed invention provides a system for distributing medical supplies that includes a record server receiving package data; a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and wherein the record server receives the verification data from the record client and correlates the verification data to the package data.

In another exemplary embodiment, the presently claimed invention provides a method for distributing medical supplies that includes storing package data corresponding to a sealed package; transmitting the sealed package to a remote site; receiving the package data from the remote site; and authorizing release of the package if the stored package data matches the received package data.

In another exemplary embodiment, the presently claimed invention provides a method for transferring electronic medical record data comprising: encapsulating an electronic medical record file so as to allow it to be viewed and to prevent it from being modified; encrypting the encapsulated electronic medical record file; transmitting the encrypted encapsulated electronic medical record file to a remote location; decrypting the encrypted encapsulated electronic medical record file at the remote location; and generating a user-readable display using the encapsulated electronic medical record file.

2. Evans

The disclosure of Evans has previously been summarized.

3. McGauley

McGauley discloses a system for maintaining and updating computerized medical records. Some of the features described in the patent are as follows:

(1) A portable data carrier 100 carried by each patient, such as a smart card, that contains the patient's complete medical history. See Abstract and column 5, lines 51 through line 67 of McGauley.

4. Portwood

Portwood discloses a system for improving compliance of a medical regimen. Some of the features described in the patent are as follows:

(1) Transmitting patient data to a physician after the patient has received a prescription and reminder data to the patient after the patient has received the prescription. Abstract.

(2) Server computer that serves as a database for prescriber computer systems. Col. 3, lines 43-49.

(3) A prescriber computer station B that provides prescription information for a patient. Column 6, line 37 through line 57.

(4) A server that validates, certifies, and distributes prescription data to a prescription distribution company, such as a pharmacy or drug wholesale company. Column 7, line 11 through 14 and lines 35-37.

5. Chudy

Chudy discloses an automated method for dispensing bulk medications with a machine-readable code. System 200 of Chudy shows a large assembly-line that is used to dispense the bulk medications from a plurality of bulk storage tablet cassettes 20 using a machine-readable code.

6. Patentability of independent claims 1 through 15, 23 and 29 through 33

Electronic medical record reliability is an issue that has delayed the migration of medical records from hardcopy formats to electronic formats. Currently, hardcopy formats of medical records can be reviewed to determine whether changes were made, such as to determine whether a practitioner went back to modify a record so as to correct a misdiagnosis or otherwise cover up a mistake. Likewise, it is difficult to inadvertently destroy a hardcopy format of a medical record, whereas electronic files can be readily erased either intentionally or inadvertently. The invention of claims 1-15, 23, and 29-33 can be used to ensure that electronic medical records have not been tampered with, and to prevent the inadvertent or intentional destruction of electronic medical records. The construction of these claims adopted by the Examiner would not provide such functionality.

Claim 1 includes "a record server having a medical record data file, the medical record data file having medical record data; a record client coupled to the record server, the record client receiving the medical record data file; and wherein the medical record data is encapsulated to prevent modification of the medical record data." The Examiner construed Claim 1 to be that disclosed at column 12, lines 56-63 and Figure 24, items 406, 408, and 410 of Evans, which discloses a wide area network connecting local area networks, and column 6, lines 44-48 of McGauley, which discloses encryption of data during transmission between two computers. The Examiner further construes claim 1 as follows in the final office action, paper no. 12, at page 12: "the McGauley reference describes encryption of medical record for the purpose of preventing and preserving the confidentiality of the individual patient's medical information. This is a clear indication that the medical information is encapsulated by encryption and cannot be modified."

As a preliminary matter, it is not clear what "the purpose of preventing and preserving the confidentiality of the individual patient's medical information" means. Presumably, this means "preventing modification," but McGauley discloses that once the file is received, it can be modified. See, e.g., McGauley, Figure 6, update object manager 118 at point of service station 110, and col. 12, lines 37-43 ("The data engine 119 controls the storage and retrieval of data from the database storage subsystem. The data engine is coupled to both the record object manager 117 and the update object manager 118. Collectively, these two object managers contain the rule sets by which medical information objects are processed according to the processing tags embedded within the data objects.") As the system of McGauley allows the

medical record data to be modified after it is received at point of service station 110 by the update object manager 118, it is clear that the encryption of McGauley is not encapsulation "to prevent modification of the medical record data." Furthermore, as previously noted, the system of Evans also provides the user with the capability to edit the medical record data. *See, e.g.*, Evans, Figures 6, 7, 8, 20, and 21. Thus, the combination of Evans and McGauley would also result in a system in which the encrypted data is decrypted at the point of service to allow modification. Finally, claim 1 does not limit encapsulation of the medical record data to a process that is performed when the medical record data is transmitted from the record server to the record client, as disclosed in McGauley, but instead provides that "the medical record data is encapsulated to prevent modification of the medical record data."

By insisting that encapsulation be construed to be synonymous with encryption, the Examiner ignores the mandate that "a patentee is free to be his own lexicographer." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (in banc), *aff'd*, 517 U.S. 370 (1996). This allows a patentee to "coin a new expression with which to communicate the invention." *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984). Although the scope of encapsulation is defined by the claims, an example of encapsulation is provided at paragraph [0036] of the specification of the present application, where it is noted that in "one exemplary embodiment, record encapsulation system 302 includes encryption algorithms that generate a value based upon the exact data structure of the entire medical record data file, such that any modifications to the medical record data file can be detected." Thus, in this exemplary embodiment, encapsulation includes the use of the value that is based on the exact data structure of the entire medical record to detect modification. Merely encrypting data that is being transmitted between two points is not encapsulation of the medical record data to prevent modification, as that data could be intercepted by a third party after transmission, modified, and then re-transmitted to the intended recipient, who would never know that the data had been modified. The Examiner's construction of this claim element as being that which is disclosed at McGauley, col. 6, lines 44-48 is therefore incorrect.

The Examiner's construction of encapsulation also violates the prohibition against construing claims in a manner that reads elements out of the claim, as it equates a process that occurs to a data record (encapsulation) with a process that occurs to a data stream as it is being transmitted (encryption). For example, claim 10 includes "encapsulating medical record data to

prevent it from being modified; assembling the medical record data into a medical record data file; receiving a request to transfer the medical record data file; and transferring the medical record data file to a remote location." The encapsulation of claim 10 thus occurs before the medical record data is assembled into a medical record data file, and before the request to transfer the medical record data file is received, unlike the process described in McGauley at column 6, lines 44-48, as relied on by the Examiner in rejecting claim 10, where the data is encrypted as it is being transmitted, only after the medical record data has been assembled into a medical record data file and after a request to transfer the medical record data file has been received. Thus, the Examiner's construction of claim 10 is also incorrect.

Claim 23 includes "a record server having an encapsulated medical record data file, the encapsulated medical record data file having medical record data that can be viewed but which cannot be modified." The Examiner again relies on the point-to-point encryption disclosed at McGauley, column 6, lines 44-48, to reject claim 23, resulting in a construction of claim 23 that is improper. The point-to-point encryption of McGauley does not allow encrypted medical record data to be viewed – it must first be decrypted. Claim 23 further includes "the record client further comprising a detail encapsulation system receiving comment data, encapsulating the comment data to prevent it from being modified, and storing the encapsulated comment data as part of the encapsulated medical record data file." Again, the construction of encapsulation to be synonymous to point-to-point encryption is incorrect, as McGauley does not disclose that the encrypted data is ever stored, much less that comment data can be encrypted separately from the medical record data file. The construction of claim 23 put forth by the Examiner does not allow the patentees to be their own lexicographer and reads limitations out of the claim, and is therefore improper and should be reversed.

Claim 29 includes "encapsulating an electronic medical record file so as to allow it to be viewed and to prevent it from being modified; encrypting the encapsulated electronic medical record file; transmitting the encrypted encapsulated electronic medical record file to a remote location; decrypting the encrypted encapsulated electronic medical record file at the remote location; and generating a user-readable display using the encapsulated electronic medical record file." Again, the Examiner construes encapsulation to be the same as the point-to-point encryption disclosed by McGauley at column 6, lines 44-48, which is flawed as described above, because a user-readable display cannot be generated using the point-to-point encrypted data, nor

does McGauley describe that the electronic medical record file is encrypted a first time and then encrypted a second time, and then transmitted, and then decrypted a first time, and that the still-encrypted electronic medical record data file is then viewed. The Examiner further admits that Evans teaches that a "nurse with the authorization . . . [can] update certain aspects" of the patient record 111 of Evans, which conclusively establishes that Evans in view of McGauley fails to disclose encapsulation to prevent modification. The construction adopted by the Examiner is incorrect, and therefore, the rejection should be reversed.

Claim 3 depends from claim 1 and includes that the record server further comprises a tracking system updating a tracking record when the medical record data file is transferred. The Examiner construes this to be that which is disclosed at Evans column 9, lines 27-37, which states that the "data manager 202 likewise tracks the location and description of patient data within the data archive 208 by associating the file name of the patient data within a patient record 220 with the patient identifier 221." However, this construction reads the limitation of "updating a tracking record when the medical record data file is transferred" out of the claim. It is clear from the cited section of Evans that what is disclosed is a process for tracking the location of data within a data archive – a tracking record for tracking when a medical record data file is transferred is not disclosed by Evans. This process can be used to create an audit log, so as to determine when a user accessed a medical record data file. The construction adopted by the Examiner would not allow an audit log to be created, and only tracks the location of data within a data archive. The construction adopted by the Examiner is incorrect, and therefore, the rejection should be reversed.

Likewise, claim 4 depends from claim 1 and includes that the record client further comprises a tracking system updating a tracking record when the medical record data file is accessed. Again, the Examiner's construction in paper no. 8 at page 4 reads this limitation out of the claim – "[t]his limitation is met by the electronic medical record system that includes server (406 Fig. 24) that are connected to client machines running applications such as Microsoft Windows to access and generating medical data (see: column 14, lines 8-16)." It is hard to understand how one could seriously assert that a server connected to client machines running applications such as Microsoft Windows equates to a tracking system updating a tracking record when the medical record data file is accessed – there is absolutely no mention of a tracking system, a tracking record, nor of the tracking record being updated. The construction adopted by

the Examiner is incorrect, and therefore, the rejection should be reversed.

Claim 5 depends from claim 1 and includes that the record client further comprises a remote data system, the remote data system generating medical record data, wherein the record client encapsulates the medical record data to prevent it from being modified. Claim 6 depends from claim 1 and includes that the record client system further comprises a detail encapsulation system receiving comment data and encapsulating the comment data to prevent it from being modified. Again, the Examiner construes encapsulation to be encryption, reading limitations out of claims 5 and 6 and denying patentees the right to be their own lexicographer. The construction adopted by the Examiner is incorrect, and therefore, the rejection should be reversed.

Claim 7 depends from claim and includes that the record server further comprises a record storage system, the record storage system storing each version of the medical record data file received by the record server. The Examiner's construction equates this to "organizing and storing of patient medical records in which are made available for access by authorized personnel." This construction would not prevent the modification or deletion of a patient medical record that has been accessed by an authorized person, whereas claim 7 would do that by storing the version of the medical record that existed prior to it being accessed by the authorized person. In this manner, if an authorized person deleted a medical record, that fact could be determine by the change between the current version and the previous version, whereas the construction adopted by the Examiner would not. Thus, the Examiner's construction improperly reads limitations out of the claim and should be reversed.

Claim 9 depends from claim 1 and includes a notification system transferring notification data to a party regarding the availability of medical record data. The Examiner construes this claim to mean "acknowledgement by the healthcare provider that a patient's record has been reviewed and adding to the medical record any necessary instructions or recommendations for treatment." This construction reads the limitation of "transferring notification data to a party regarding the availability of medical record data" out of the claim – if the transfer of the medical record itself constitutes the notification, then there is no need for transferring notification data. The construction adopted by the Examiner is incorrect, and therefore, the rejection should be reversed.

Claim 12 depends from claim 10 and includes that assembling the medical record data

into the medical record data file further comprises storing a tracking record with the medical record data file. Again, the construction adopted by the Examiner fails to address the tracking record as being separate from the medical record data file and being used to **track** something. The Examiner construes claim 12 as an "electronic medical record system which stores and updates patient records upon a nurses or physician entry of information," citing to column 3, lines 9-16 and column 5, lines 29-40 of Evans. However, the nurses or physician's entry of information is made to the electronic medical record, ***not*** to the tracking record. The Examiner's construction improperly reads limitations out of the claim, and should be reversed.

Claim 13 depends from claim 10 and includes generating notification data at the remote location. The Examiner's construction of claim 13 is incorrect for the same reasons previously discussed in regards to claim 9.

Claim 14 depends from claim 10 and includes accessing the medical record data file at the remote location; and updating a tracking record to show that the medical record data file has been accessed at the remote location. The Examiner's construction of claim 14 is incorrect for the same reasons previously discussed in regards to claim 12.

Claim 15 depends from claim 10 and includes receiving medical record data at the remote location; encapsulating the medical record data to prevent the medical record data from being modified; and updating the medical record data file to include the medical record data. The Examiner's construction of claim 15 is incorrect for the same reasons previously discussed in regards to claim 1.

Claim 32 depends from claim 1 and includes that the medical record client operates in unattended mode, so as to allow the medical record data file to be received without user input. The Examiner's construction of claim 32 is incorrect for the same reasons previously discussed in regards to claim 25.

In summary, the Examiner's construction of claims 1-15, 23, and 29-33 fails to allow the patentees to be their own lexicographer and reads limitations out of the claims, for the numerous reasons described above. The rejection of claims 1-15, 23, and 29-33 should therefore be reversed.

7. Patentability of claims 16 through 22, 34, and 35

Independent claims 16 and 20 and the associated dependent claims are drawn to a system

that can be used in one exemplary embodiment to allow prescription drugs to be dispensed at a remote location without requiring a licensed pharmacist to be present at that location. Under current laws, a licensed pharmacist must supervise the dispensing of prescription drugs. While mail or delivery services can then be used, there are many locations such as nursing homes where large numbers of identical prescriptions are typically dispensed. In these locations, the prior art would require the prescription data for each such prescription to be transmitted from a physician at the location to a pharmacist, and for the pharmacist to individually supervise the packaging and delivery of each prescription package. Claims 16 and 20 and the claims that depend from them provide a system whereby a pharmacist can supervise the creation of a large number of such packages, which can then be transmitted to a remote location and dispensed from that remote location as soon as the prescription is ordered by the physician and remotely verified by the pharmacist. The Examiner's construction of claims 16 and 20 and the claims that depend from them reads limitations out of the claims to yield a system that would require a licensed pharmacist to receive the prescription, prepare the package, and then supervise the delivery of each package to each patient.

Claim 16 includes a "system for distributing medical supplies comprising: a record server receiving package data; a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and wherein the record server receives the verification data from the record client and correlates the verification data to the package data." The Examiner construed claim 16 to be that disclosed by the combination of Evans at column 14, lines 8-16 and Portwood at the abstract, column 3 lines 43-49, and column 7 lines 35-37, noting that Portwood discloses "a server computer communicating with other prescriber computer to transfer prescription data to the server for validation, certification, and distribution," and further asserting that "prescriptions are a form of 'medical supplies.'" The Examiner admitted that Evan fails to disclose the claim element of receiving package data from the record server with verification data and correlating the verification data to the package data, but alleged that the cited sections of Portwood disclose those elements.

As previously discussed, the cited sections of Portwood disclose a prescriber computer station B that provides prescription information for a patient, and a prescription distribution company, such as a pharmacy or drug wholesale company. As disclosed at column 6, line 66 to column 7 line 3 of Portwood, the paths shown in Figure 2 of Portwood show "a preferred use of

the server computer station A to obtain a preferred flow of data, reports, and messages amongst the physician, the prescription distribution service organization, the patient, and the prescription payer. The various ***channels of information*** flow as described below as indicated by the information flow numbers in FIG. 2." (Emphasis added). In this regard, it appears that the Examiner may have confused "prescription data" with the package of prescription drugs that are assembled based on the prescription data, as both are loosely referred to as the "prescription" in Portwood. However, it is indisputable that Portwood fails to disclose a sealed package.

The Examiner's construction of the claim, based on the disclosed portions of Evans and Portwood, is therefore incorrect, because it reads limitations (such as a sealed package) out of the claim. Claim 16 includes "a record server receiving package data." Portwood clearly states that information only flows on the paths shown in Figure 2 of Portwood, and described at column 7, lines 6-62 of Portwood. Thus, no package (and therefore, no package data) is created until the prescription data reaches the prescription distribution service. It therefore follows that "a record client coupled to the record server, the record client receiving the package data from the record server and verification data" is missing from Portwood – neither the prescriber or the payor would receive the prescription package from the prescription distribution service, which leaves only the patient. Data path 5 to the patient is only generated before the prescription package is created by the prescription distribution service, and pertains to messages that are scheduled to be sent to the patient regarding "general information, prescription history, and prescription calendar" – not verification data that is received by the record server and correlated to the package data." Data path 8 is only the response to these messages, and does not include verification data that is correlated to package data. The Examiner's construction of the claim reads out the claim limitations that pertain to the use of verification data to verify that the package data has been properly dispensed to the correct patient, and should be reversed.

Claim 17 depends from claim 16 and includes an inventory tracking system receiving the verification data and incrementing order data. Neither Portwood nor Evans disclose such a system, which can be used to determine when a new batch of sealed prescription packages needs to be created and sent to a remote location such as a nursing home. Claim 18 depends from claim 16 and includes a record encapsulation system receiving the verification data and encapsulating the verification data in a medical record data file. The Examiner again construes encapsulation to be the point-to-point encryption disclosed by McGauley, which improperly fails

to allow the applicants to be their own lexicographer and reads limitations out of the claim. Claim 19 depends from claim 16 and includes a remote data system generating counseling data and transmitting the counseling data to the record server. Counseling from a licensed pharmacist is required by law where a prescription drug is being dispensed to a patient for the first time. The Examiner's construction of claim 19 as being that which is disclosed at Evans, column 2, lines 45-58 would require an authorized healthcare provider to be physically present at the remote system, and thus reads limitations out of the claim. The construction of these claims adopted by the Examiner is incorrect and should be reversed.

The Examiner's construction of claims 20-22 likewise reads limitations out of the claims. In regards to the element of "storing package data corresponding to a sealed package," the Examiner construes this to be disclosed by Portwood, column 2, lines 60-66, which states "a system to facilitate compliance with a prescribed medical regimen is provided, which comprises a computer system having a data storage unit containing stored pharmaceutical data, a central processing unit (CPU) programmed and operatively connected to the data storage unit to further store in the data storage unit patient data and patient prescription data." There is no mention of a sealed package at all in the cited section of Portwood, nor anywhere else in Portwood. Portwood does not address one problem solved by the invention, namely, that a licensed pharmacist must be able to verify that prescription drugs have been dispensed to the correct patient. The prior art requires the licensed pharmacist to travel to patients that are unable to travel to the pharmacist, such as patients in nursing homes, whereas the invention allows the pharmacist to receive suitable verification data to confirm that the correct prescription drug has been provided to the correct patient. Nothing in Portwood suggests that prescriptions are dispensed in any manner other than using the process required by law, namely, of having a licensed pharmacist visually verify receipt of the prescription drug to the patient identified by the prescription received from the doctor.

In regards to the element of "transmitting the sealed package to a remote site" of claim 20, the Examiner construes this to be disclosed by the abstract and column 5, lines 7-10 of Portwood. The abstract states that a prescription drug service is notified to **deliver** prescribed drugs to the patient – again, not only failing to mention anything about a sealed package, but also failing to disclose anything other than the traditional method of using a licensed pharmacist to dispense the prescribed drugs. Column 5, lines 7-10 likewise only refers to a prescription

distribution system D that enables quicker delivery, failing to mention anything about sealed packages and inferring nothing other than the process required by law that a licensed pharmacist must dispense prescription drugs directly to the patient, such as in person, by mailing it to that person's address, or by delivering it to that person's address.

In regards to "authorizing release of the package if the stored package data matches the received package data," the Examiner construes this to be disclosed by column 3, lines 36-41 of Portwood, which state that "the CPU is further programmed to generate a prescription delivery message, and wherein the system further comprises a message receiving unit operatively connected to the CPU to receive the prescription delivery message." The cited section of Portwood utterly fails to mention anything about authorizing release of a package or determining whether stored package data matches received package data. Furthermore, it appears that the Examiner is again confusing the prescription data with the prescription package, as the only subsequent mention of this "prescription delivery message" other than the cited section from the Summary of the Invention section of Portwood occurs at column 18, lines 34 through 46, which refer to the transmission of prescription data to the prescription delivery system D, where a licensed pharmacist must assemble a package containing the prescribed drug and dispense the prescribed drug to the patient identified by the prescription data. Again, the Examiner's construction of the claim reads out the limitations of determining whether the stored package data matches the received package data, and authorizing release of the package if it does.

In regards to the element of "receiving the package data from the remote site," the Examiner construes this to be disclosed by Evans, column 2, lines 45-47 (which refers to providing instant access to a patient's electronic medical record by **authorized healthcare providers**) and column 10, lines 18-23 (which refers to receiving patient data from external sources). Evans, like Portwood, utterly fails to disclose sealed packages, storing package data corresponding to the sealed package, transmitting the sealed package to a remote site, and authorizing release of the package if the stored package data matches the received package data. The cited sections of Evans require authorized healthcare providers to be present at any location where the patient's electronic medical record is accessed. The Examiner's construction thus reads elements out of the claim that allow the licensed pharmacist to authorize release of prescribed drugs at a remote site without being present at the remote site.

Claim 21 depends from claim 20 and includes counseling a patient if the patient has not

received the medical supplies before and generating counseling data. Again, the Examiner's construction would require a licensed pharmacist to be present to provide the counseling, and reads elements out of the claim that would allow the licensed pharmacist to verify that the correct counseling data has been provided from a remote location. Claim 22 also depends from claim 20 and includes incrementing order data after the package is released. The Examiner's construction reads on the prior art, which requires a pharmacist to prepare each package after receiving the prescription data, and reads elements out of the claim that allow a number of packages containing predetermined dosages of prescription to be created and distributed to patients at locations where a licensed pharmacist is not present.

Claim 34 depends from claim 16 and includes a data reader that reads the verification data from the package. The Examiner, using nothing more than the claims as a blueprint, construes claim 34 to be the same as Chudy, column 14, lines 54-63, and figure 25, items 119 and 125, stating that one of ordinary skill in the art would have combined Chudy with Evans and Portwood to yield the invention of claim 34. As previously discussed, system 200 of Chudy shows a large assembly-line that is used to dispense the bulk medications from a plurality of bulk storage tablet cassettes 20 using a machine-readable code, which would necessarily require a licensed pharmacist to be present. The data reader of claim 34 reads verification data from a package at the point where it is dispensed – why would anyone go through the process of receiving package data at a record server; receiving the package data from the record server at a record client with verification data, and receiving the verification data from the record client at the record server and correlating the verification data to the package data if there was a licensed pharmacist operating system 200 of Chudy at the location of the record client? It is clear that the Examiner performed a simple search for the term "data reader" in conjunction with "medication" or some other similar terms, using the claim as a guide, to find a reference that could be combined with Evans and Portwood, because there would be no motivation to try and use the data reader in a complex assembly line such as Chudy in a remote location to dispense packages that were already assembled by a licensed pharmacist. The Examiner's construction of this claim is incorrect for the reasons previously discussed in regards to claim 16, not to mention that the Examiner used the claim as a blueprint to hunt for a reference to combine with Evans and Portwood so as to provide the missing element. The rejection of this claim should be reversed.

Claim 35 depends from claim 16 and includes an image data capture device that

generates image data, and the verification data includes the image data. Again, the Examiner's construction of this claim would require a licensed pharmacist to be present, and is incorrect and should be reversed because it reads limitations out of the claim.

8. Patentability of claims 2, 11, 23, 31, and 33

One of the problems previously noted with electronic medical record data is that a practitioner can mistakenly obtain the file for another patient, by either misspelling the patient's name, entering the wrong social security number, or by otherwise making errors. Claim 2 depends from claim 1 and includes "a sync system verifying that the record client has received a sync file before transferring the medical record data file." Again, the term "sync file" is not a term of art, and the patentees should be allowed to be their own lexicographers. One exemplary embodiment of a sync file is defined in the specification at paragraph [0023]:

> In one exemplary embodiment, sync system 108 can transmit the entire medical record data file for a patient to record client 104a or 104b, such that record client 104a or 104b stores the latest version of the entire medical record data file regardless of whether any version of that file exists on record client 104a or 104b. In another exemplary embodiment, sync system 108 can first determine which medical record data file or files a record client 104a or 104b has for a patient, and can then transmit only files or portions of files that have been changed, new files, or other suitable files. In this manner, sync system 108 ensures that the medical record data files stored on record client 104a and 104b are the most recent medical files, and further that sufficient files exist to particularly identify any patient, so as to prevent inadvertent misdiagnosis, misplacement or misfiling of medical record data files, or other problems.

The Examiner construes claim 2 as follows: "This feature is met by the electronic medical record system including web servers (406, Fig. 24) that allow patient data to be transfer between external source as well as updating the patient record obviously suggesting that the comparing and checking of medical data take place to verify that an up-to-date medical record is available." However, web servers do not verify that sync data has been received before transferring file data. As previously described, the patient record 111 of Evans is transferred from the patient data repository 102 to a point of care system 100, but Evans does not disclose verifying that the record client has received sync data before transferring the patient record 111.

Thus, if two patients had the same name, the wrong file could easily be transferred without detection. Likewise, Evans does not store the patient record 111 at the remote system, but returns it as patient record 119 to patient data repository 102. The construction of claim 2 adopted by the Examiner thus reads limitations out of the claim and does not allow the patentees to be their own lexicographers, and should be reversed.

Claim 11 depends from claim 10 and includes that transferring the medical record data file to the remote location further comprises transferring a sync file to the remote location. The construction of claim 11 adopted by the Examiner reads limitations out of the claim and does not allow the patentees to be their own lexicographers for the reasons discussed in regards to claim 2, and should be reversed.

Claim 23 includes a record server having an encapsulated medical record data file, the encapsulated medical record data file having medical record data that can be viewed but which cannot be modified; a record client coupled to the record server, the record client receiving the encapsulated medical record data file; a sync system verifying that the record client has received sync data before transferring the encapsulated medical record data file; the record server further comprising a tracking system updating a tracking record when the encapsulated medical record data file is transferred; the record client further comprising a tracking system updating a tracking record when the encapsulated medical record data file is accessed; the record client further comprising a detail encapsulation system receiving comment data, encapsulating the comment data to prevent it from being modified, and storing the encapsulated comment data as part of the encapsulated medical record data file; and wherein the record client operates in unattended mode such that the encapsulated medical record data file can be received without an operator present. The construction of claim 23 adopted by the Examiner reads limitations out of the claim and does not allow the patentees to be their own lexicographers for the reasons discussed in regards to the previous claims, and should be reversed.

Claim 31 depends from claim 2 and includes that the sync file is a patient file. Claim 33 depends from claim 11 and includes that transferring the sync file comprises creating a patient folder. The construction of claims 31 and 33 adopted by the Examiner reads limitations out of the claim and does not allow the patentees to be their own lexicographers for the reasons discussed in regards to claim 2, and should be reversed.

9. Summary

For the reasons set forth above, Appellant submits that the Examiner's construction of the claims is improper on the grounds that it reads elements out of the claims and that it does not allow the applicants to be their own lexicographers, and that Appellant's properly construed claimed invention is indeed novel and unobvious over the applied references and the art of record.

Accordingly, the Examiner's rejections must be REVERSED, and claims 1-35 must be allowed.

IX. APPENDIX OF CLAIMS (37 C.F.R. § 1.192(c)(9))

The text of the claims involved in the appeal are as follows:

1. A system for transferring electronic medical files comprising:

a record server having a medical record data file, the medical record data file having medical record data;

a record client coupled to the record server, the record client receiving the medical record data file; and

wherein the medical record data is encapsulated to prevent modification of the medical record data.

2. The system of claim 1 wherein the record server further comprises a sync system verifying that the record client has received a sync file before transferring the medical record data file.

3. The system of claim 1 wherein the record server further comprises a tracking system updating a tracking record when the medical record data file is transferred.

4. The system of claim 1 wherein the record client further comprises a tracking system updating a tracking record when the medical record data file is accessed.

5. The system of claim 1 wherein the record client further comprises a remote data system, the remote data system generating medical record data, wherein the record client encapsulates the medical record data to prevent it from being modified.

6. The system of claim 1 wherein the record client system further comprises a detail encapsulation system receiving comment data and encapsulating the comment data to prevent it from being modified.

7. The system of claim 1 wherein the record server further comprises a record storage system, the record storage system storing each version of the medical record data file received by the record server.

8. The system of claim 1 wherein the record server further comprises an excerpt transfer system, the excerpt transfer system receiving medical record excerpt data and transferring it to a predetermined recipient.

9. The system of claim 1 further comprising a notification system transferring notification data to a party regarding the availability of medical record data.

10. A method for transferring electronic medical files comprising:

encapsulating medical record data to prevent it from being modified;

assembling the medical record data into a medical record data file;

receiving a request to transfer the medical record data file; and

transferring the medical record data file to a remote location.

11. The method of claim 10 wherein transferring the medical record data file to the remote location further comprises transferring a sync file to the remote location.

12. The method of claim 10 wherein assembling the medical record data into the medical record data file further comprises storing a tracking record with the medical record data file.

13. The method of claim 10 further comprising generating notification data at the remote location.

14. The method of claim 10 further comprising:

accessing the medical record data file at the remote location; and

updating a tracking record to show that the medical record data file has been accessed at the remote location.

15. The method of claim 10 further comprising:

receiving medical record data at the remote location;

encapsulating the medical record data to prevent the medical record data from being modified; and

updating the medical record data file to include the medical record data.

16. A system for distributing medical supplies comprising:

a record server receiving package data;

a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and

wherein the record server receives the verification data from the record client and correlates the verification data to the package data.

17. The system of claim 16 further comprising an inventory tracking system receiving the verification data and incrementing order data.

18. The system of claim 16 wherein the record server further comprises a record encapsulation system receiving the verification data and encapsulating the verification data in a medical record data file.

19. The system of claim 16 wherein the record client further comprises a remote data system, the remote data system generating counseling data and transmitting the counseling data to the record server.

20. A method for distributing medical supplies comprising:

storing package data corresponding to a sealed package;

transmitting the sealed package to a remote site;

receiving the package data from the remote site; and

authorizing release of the package if the stored package data matches the received package data.

21. The system of claim 20 wherein receiving the package data from the remote site further comprises:

counseling a patient if the patient has not received the medical supplies before; and

generating counseling data.

22. The method of claim 20 further comprising incrementing order data after the package is released.

23. A system for transferring electronic medical files comprising:

a record server having an encapsulated medical record data file, the encapsulated medical record data file having medical record data that can be viewed but which cannot be modified;

a record client coupled to the record server, the record client receiving the encapsulated medical record data file;

a sync system verifying that the record client has received sync data before transferring the encapsulated medical record data file;

the record server further comprising a tracking system updating a tracking record when the encapsulated medical record data file is transferred;

the record client further comprising a tracking system updating a tracking record when the encapsulated medical record data file is accessed;

the record client further comprising a detail encapsulation system receiving comment data, encapsulating the comment data to prevent it from being modified, and storing the encapsulated comment data as part of the encapsulated medical record data file; and

wherein the record client operates in unattended mode such that the encapsulated medical record data file can be received without an operator present.

24. A method for transferring electronic medical data comprising:

determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system;

transferring the electronic medical data to the patient file if it is determined that it exists;

creating the patient file with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system; and

transferring the electronic medical data to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system.

25. The method of claim 24 wherein the remote system operates in an unattended mode that allows the electronic medical data to be transferred without operator input.

26. The method of claim 25 wherein the remote system receives electronic medical data for two or more users in unattended mode, and each user must enter a user-specific access ID to access the electronic medical data for that user.

27. A method for transferring electronic medical record data comprising:

extracting an excerpt of the electronic medical record data from an electronic medical record data file at a first location;

transmitting the excerpt to a remote location;

receiving comment data associated with the excerpt;

transmitting the comment data to the first location.

28. The method of claim 27 wherein extracting an excerpt of the electronic medical record data from the electronic medical record data file comprises removing user-readable patient identifying data.

29 A method for transferring electronic medical record data comprising:

encapsulating an electronic medical record file so as to allow it to be viewed and to prevent it from being modified;

encrypting the encapsulated electronic medical record file;

transmitting the encrypted encapsulated electronic medical record file to a remote location;

decrypting the encrypted encapsulated electronic medical record file at the remote location; and

generating a user-readable display using the encapsulated electronic medical record file.

30. The method of claim 29 wherein the electronic medical record file is an image data file.

31. The system of claim 2 wherein the sync file is a patient file.

32. The system of claim 1 wherein the medical record client operates in unattended mode, so as to allow the medical record data file to be received without user input.

33. The method of claim 11 wherein transferring the sync file comprises creating a patient folder.

34. The system of claim 16 wherein the record client further comprises a data reader that reads the verification data from the package.

35. The system of claim 16 wherein the record client further comprises an image data capture device that generates image data, and the verification data includes the image data.

X. OTHER MATERIAL THAT APPELLANT CONSIDERS NECESSARY OR DESIRABLE

See Appendix:

A. Evans - U.S. Patent No. 5,924,074
B. McGauley - U.S. Patent No. 5,899,998
C. Portwood – U.S. Patent No. 6,305,377
D. Chudy – U.S. Patent No. 6,370,841

Respectfully submitted,

7/8/07
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PATENT & TRADEMARK OFFICE JUL 11 2003 OIPE JC176

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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United States Patent [19]

Evans

[11] Patent Number: 5,924,074

[45] Date of Patent: Jul. 13, 1999

[54] **ELECTRONIC MEDICAL RECORDS SYSTEM**

[75] Inventor: **Jae A. Evans**, Carlsbad, Calif.

[73] Assignee: **Azron Incorporated**, San Diego, Calif.

[21] Appl. No.: **08/721,182**

[22] Filed: **Sep. 27, 1996**

[51] **Int. Cl.**[6] **G06K 07/00**

[52] **U.S. Cl.** **705/3**; 705/2; 707/1; 707/3; 707/10

[58] **Field of Search** 705/3, 2; 707/1, 707/3, 10, 100, 102, 104

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,872,448	3/1975	Mitchell, Jr. .	
5,416,695	5/1995	Stutman et al.	600/300
5,659,741	8/1997	Eberhardt	707/104

OTHER PUBLICATIONS

Declaration of Hollon H. Bridges, Jr., Dated Sep. 24, 1996, pp. 1–2.

Declaration of Jae A. Evans, Dated Sep. 27, 1996, pp. 1–5 including Exhibit A, 1 p.

Declaration of Marion Neal, Dated Sep. 26, 1996, pp. 1–3.

Declaration of David Printz, Dated Sep. 26, 1996, pp. 1–2.

Kleinholz et al., "Supporting Cooperative Medicine: The Bermed Project," *IEEE MultiMedia,* vol. 1, No. 4, Dec. 21, 1994 pp. 44–53.

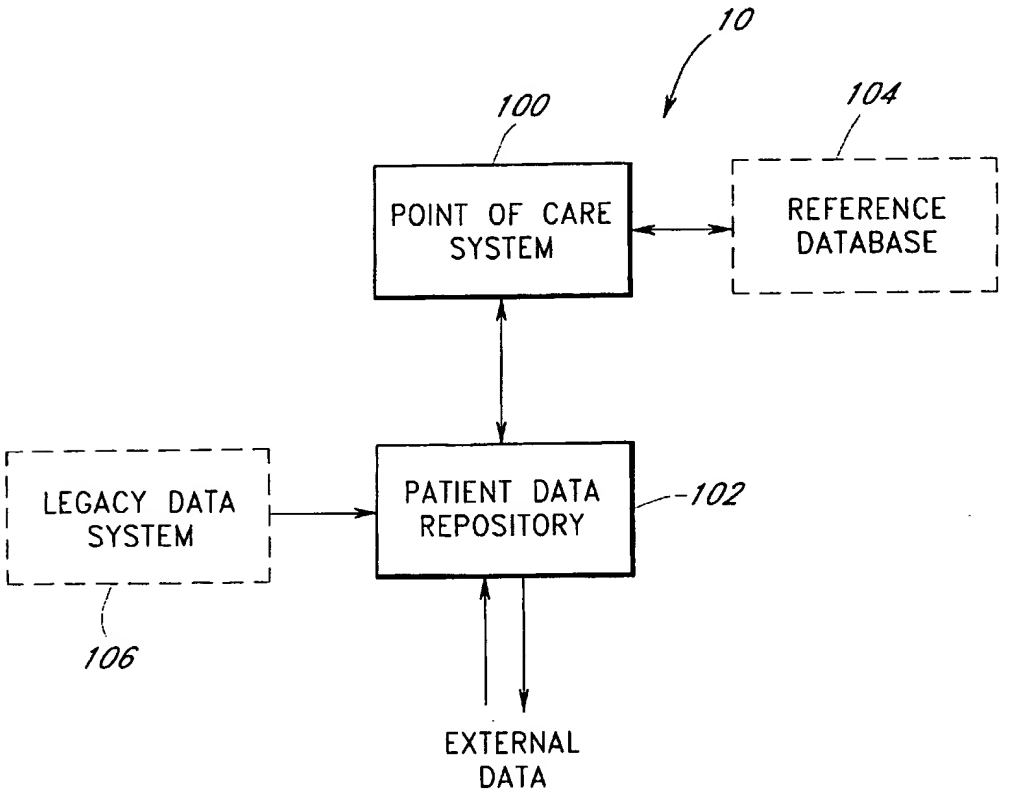
Primary Examiner—Thomas R. Peeso

Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear LLP

[57] **ABSTRACT**

A medical records system that creates and maintains all patient data electronically. The system captures patient data, such as patient complaints, lab orders, medications, diagnoses, and procedures, at its source at the time of entry using a graphical user interface having touch screens. Using pen-based portable computers with wireless connections to a computer network, authorized healthcare providers can access, analyze, update and electronically annotate patient data even while other providers are using the same patient record. The system likewise permits instant, sophisticated analysis of patient data to identify relationships among the data considered. Moreover, the system includes the capability to access reference databases for consultation regarding allergies, medication interactions and practice guidelines. The system also includes the capability to incorporate legacy data, such as paper files and mainframe data, for a patient.

46 Claims, 26 Drawing Sheets



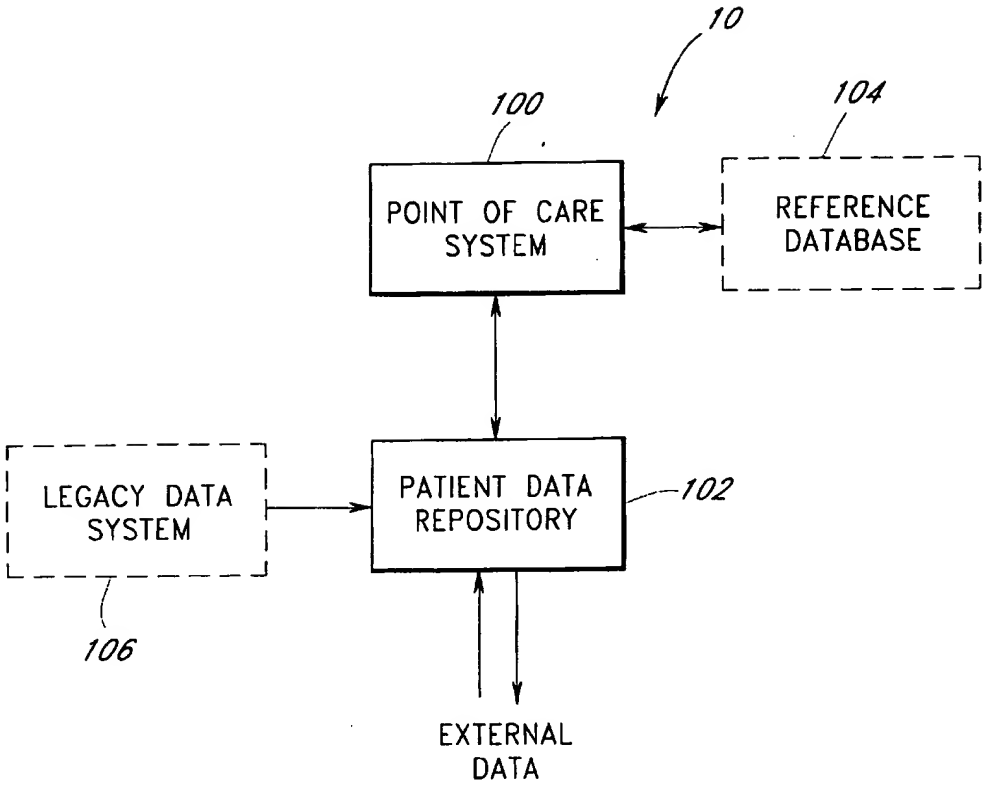

10
100
104
POINT OF CARE SYSTEM
REFERENCE DATABASE
LEGACY DATA SYSTEM
PATIENT DATA REPOSITORY
102
106
EXTERNAL DATA

FIG. 1

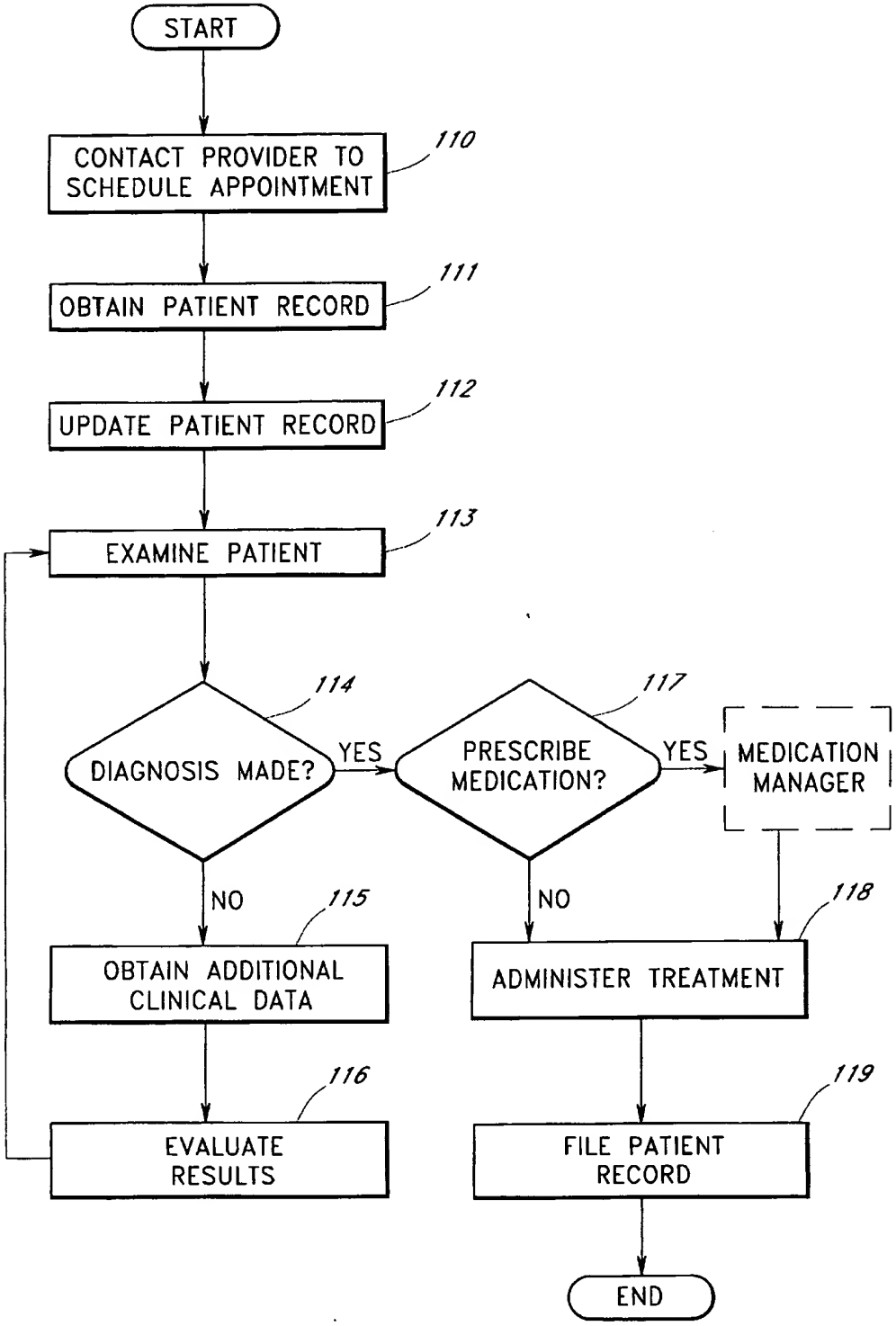

START
CONTACT PROVIDER TO SCHEDULE APPOINTMENT
110
OBTAIN PATIENT RECORD
111
UPDATE PATIENT RECORD
112
EXAMINE PATIENT
113
DIAGNOSIS MADE?
114
YES
PRESCRIBE MEDICATION?
117
YES
MEDICATION MANAGER
NO
115
NO
118
OBTAIN ADDITIONAL CLINICAL DATA
ADMINISTER TREATMENT
EVALUATE RESULTS
116
FILE PATIENT RECORD
119
END

FIG. 2

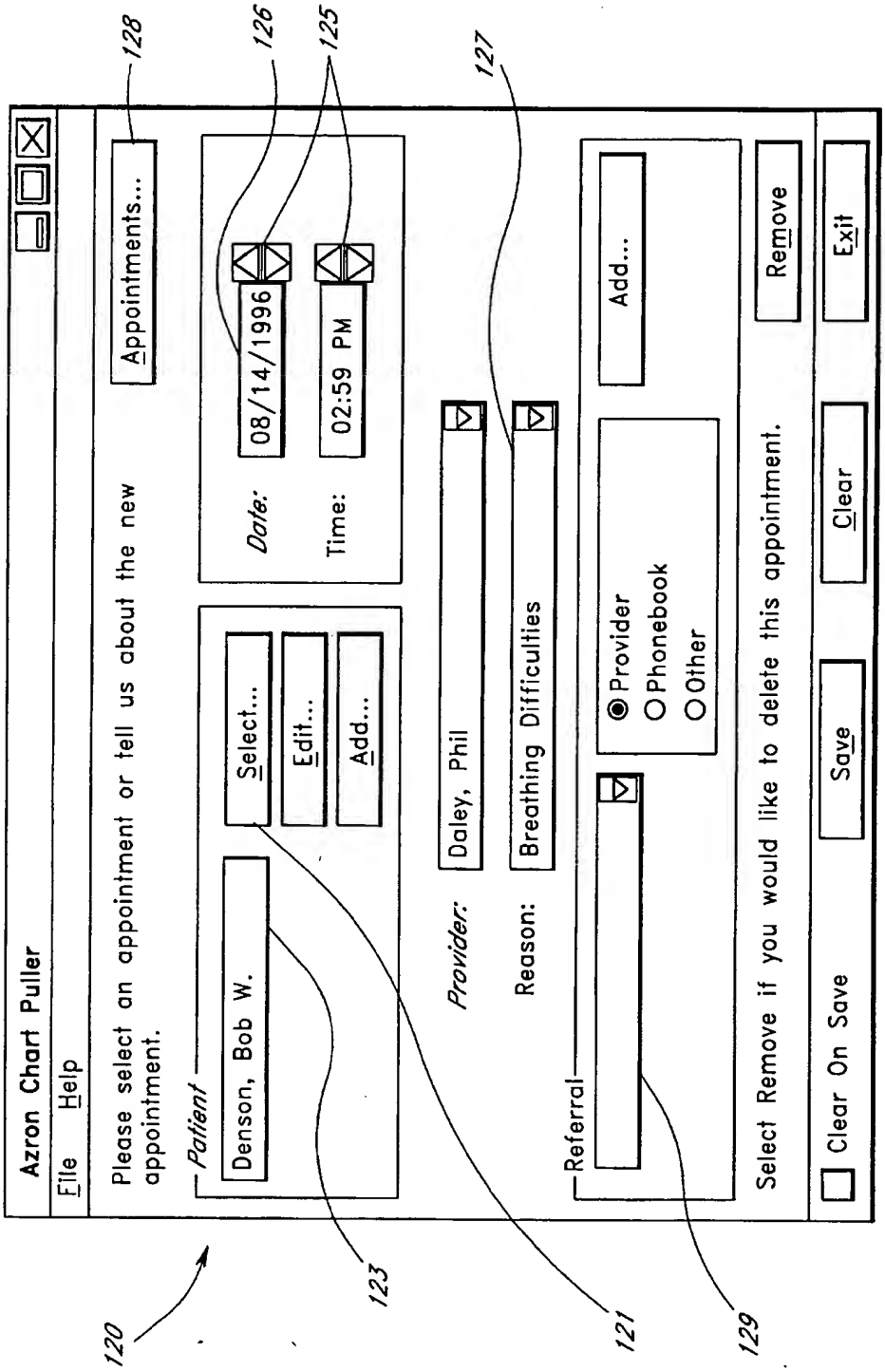

Azron Chart Puller
File Help
Please select an appointment or tell us about the new appointment.
Appointments...
Patient
Denson, Bob W.
Select...
Edit...
Add...
Date:
08/14/1996
Time:
02:59 PM
Provider:
Daley, Phil
Reason:
Breathing Difficulties
Referral
Add...
Provider
Phonebook
Other
Select Remove if you would like to delete this appointment.
Remove
Exit
Clear On Save
Save
Clear
120
123
121
129
125
126
127
128

FIG. 3

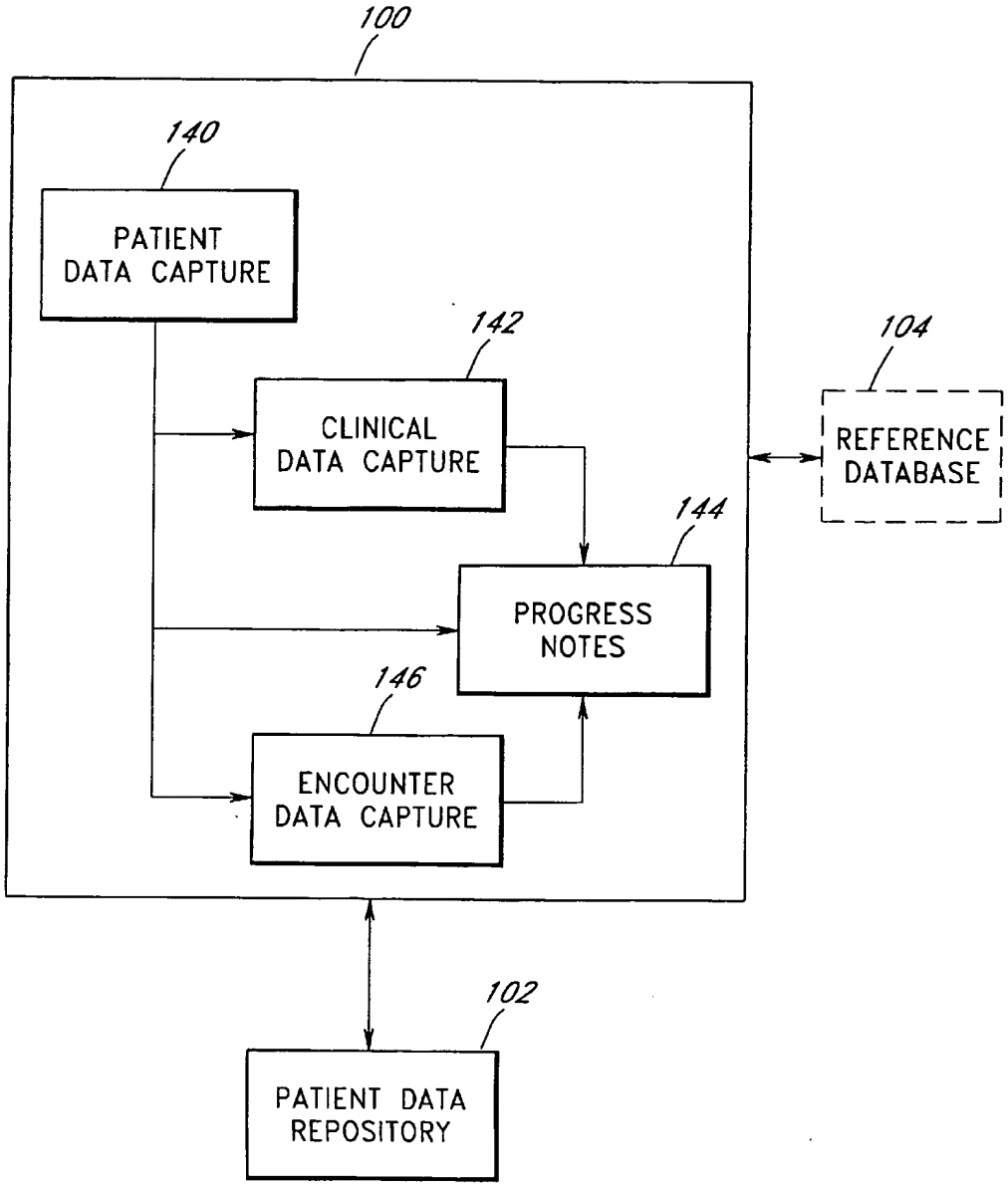

100
140
PATIENT DATA CAPTURE
142
CLINICAL DATA CAPTURE
104
REFERENCE DATABASE
144
PROGRESS NOTES
146
ENCOUNTER DATA CAPTURE
102
PATIENT DATA REPOSITORY

FIG.4

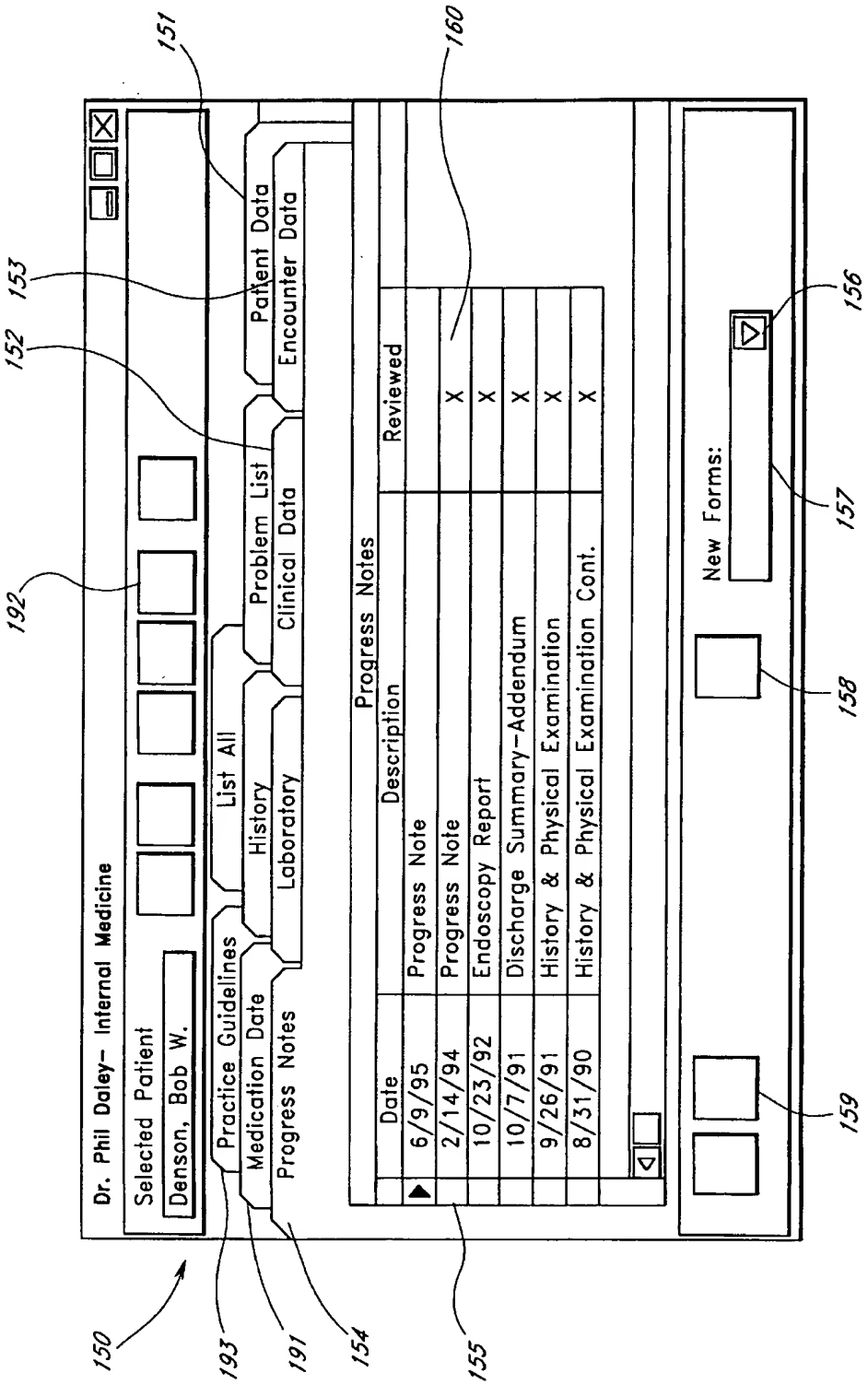

Dr. Phil Daley– Internal Medicine
Selected Patient
Denson, Bob W.
Practice Guidelines
Medication Data
Progress Notes
List All
History
Laboratory
Problem List
Clinical Data
Patient Data
Encounter Data
Progress Notes
Date
Description
Reviewed
6/9/95
Progress Note
2/14/94
Progress Note
X
10/23/92
Endoscopy Report
X
10/7/91
Discharge Summary–Addendum
X
9/26/91
History & Physical Examination
X
8/31/90
History & Physical Examination Cont.
X
New Forms:
150
151
152
153
154
155
156
157
158
159
160
191
192
193

FIG.5

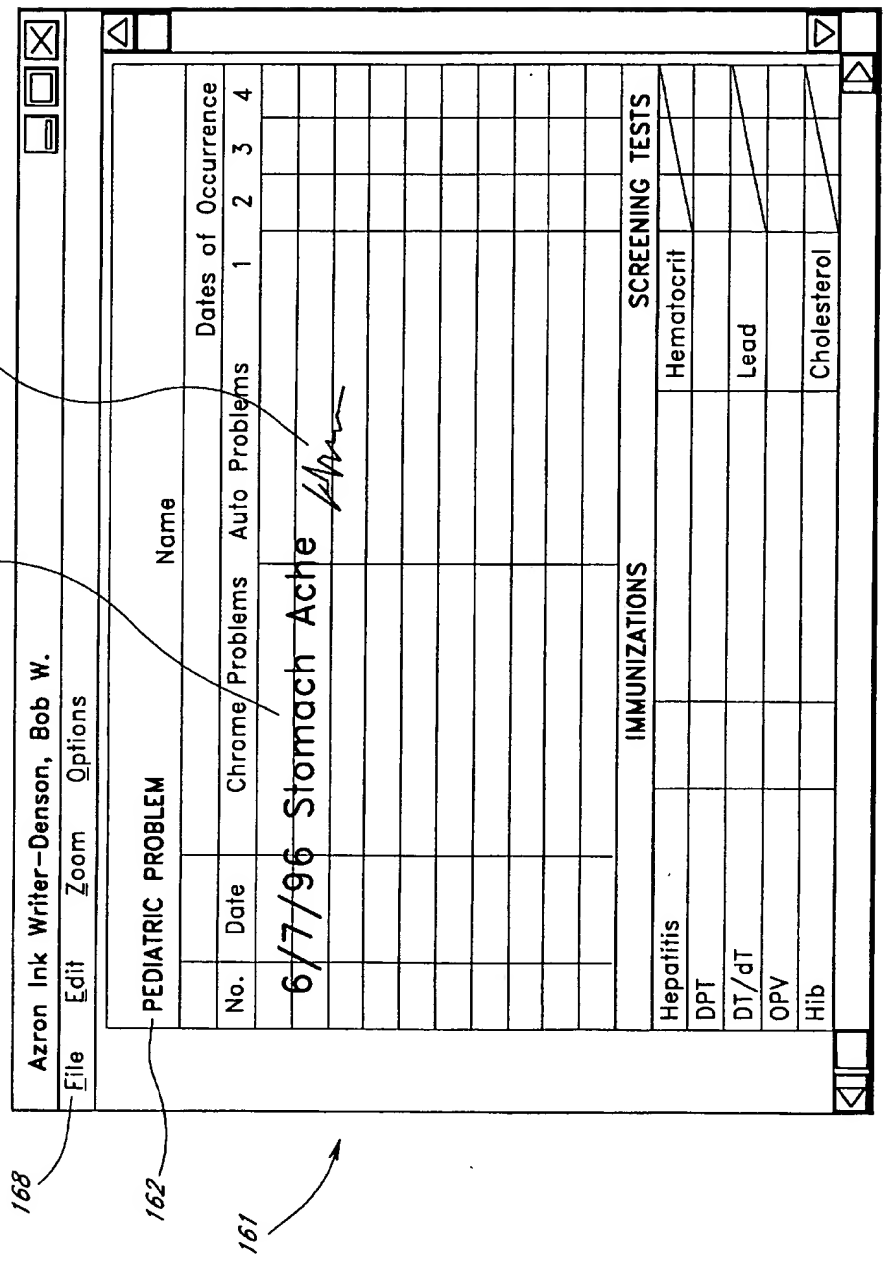

Azron Ink Writer–Denson, Bob W.
File Edit Zoom Options
PEDIATRIC PROBLEM
Name
No. Date Chrome/Problems Auto Problems
Dates of Occurrence 1 2 3 4
6/7/96 Stomach Ache
IMMUNIZATIONS
Hepatitis
DPT
DT/dT
OPV
Hib
SCREENING TESTS
Hematocrit
Lead
Cholesterol
166
164
168
162
161

FIG. 6

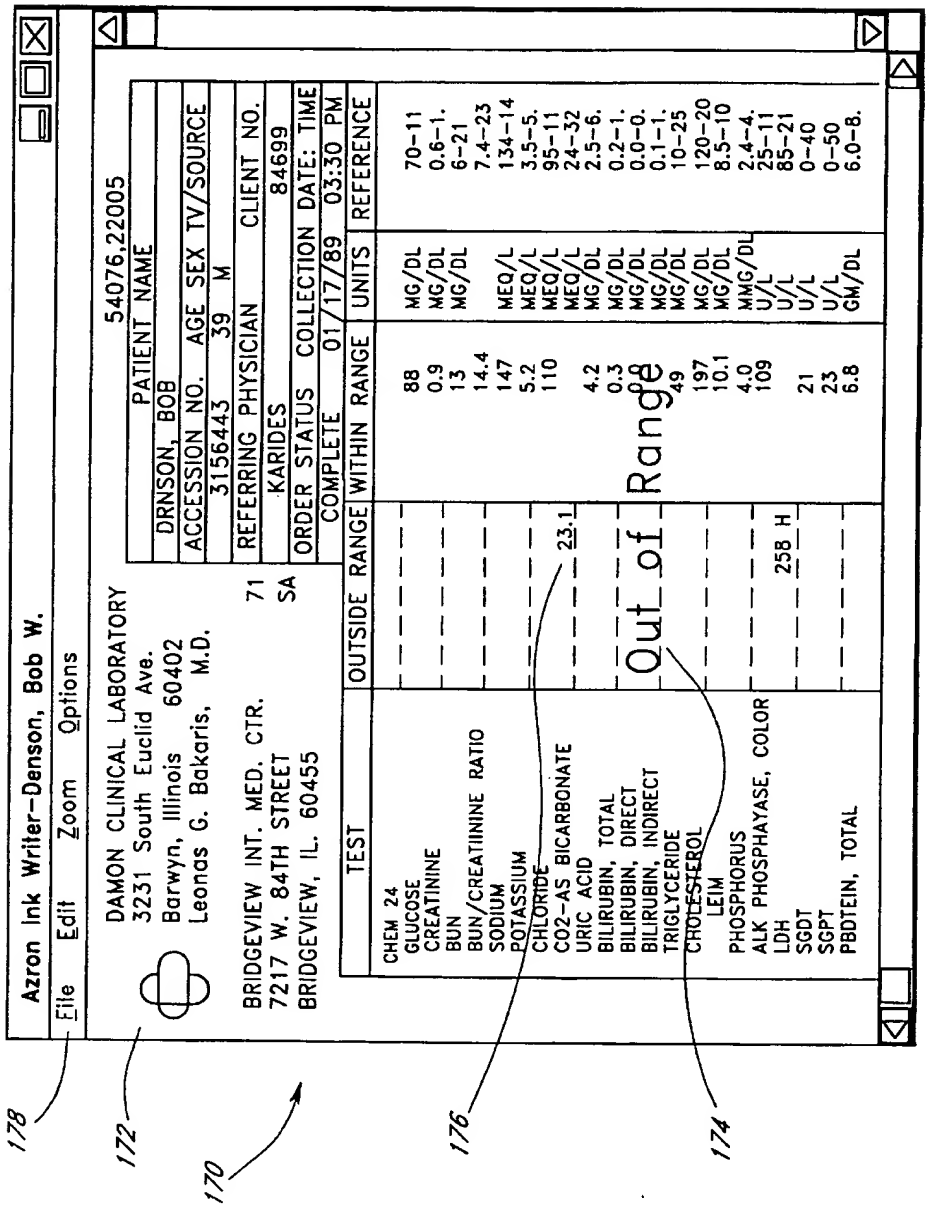

Azron Ink Writer-Denson, Bob W.
File Edit Zoom Options
DAMON CLINICAL LABORATORY
3231 South Euclid Ave.
Barwyn, Illinois 60402
Leonas G. Bakaris, M.D.
BRIDGEVIEW INT. MED. CTR.
7217 W. 84TH STREET
BRIDGEVIEW, IL. 60455
54076,22005
PATIENT NAME
DRNSON, BOB
ACCESSION NO. AGE SEX TV/SOURCE
3156443 39 M
REFERRING PHYSICIAN CLIENT NO.
KARIDES 84699
ORDER STATUS COLLECTION DATE: TIME
COMPLETE 01/17/89 03:30 PM
TEST OUTSIDE RANGE WITHIN RANGE UNITS REFERENCE
CHEM 24
GLUCOSE 88 MG/DL 70-11
CREATININE 0.9 MG/DL 0.6-1.
BUN 13 MG/DL 6-21
BUN/CREATIININE RATIO 14.4 7.4-23
SODIUM 147 MEQ/L 134-14
POTASSIUM 5.2 MEQ/L 3.5-5.
CHLORIDE 110 MEQ/L 95-11
CO2-AS BICARBONATE 23.1 MEQ/L 24-32
URIC ACID 4.2 MG/DL 2.5-6.
BILIRUBIN, TOTAL 0.3 MG/DL 0.2-1.
BILIRUBIN, DIRECT 0.0 MG/DL 0.0-0.
BILIRUBIN, INDIRECT 0.1 MG/DL 0.1-1.
TRIGLYCERIDE 49 MG/DL 10-25
CHOLESTEROL 197 MG/DL 120-20
LEIM 10.1 MG/DL 8.5-10
PHOSPHORUS 4.0 MMG/DL 2.4-4.
ALK PHOSPHAYASE, COLOR 109 U/L 25-11
LDH 258 H U/L 85-21
SGDT 21 U/L 0-40
SGPT 23 U/L 0-50
PBDTEIN, TOTAL 6.8 GM/DL 6.0-8.
Out of Range
71
SA
178
172
170
176
174

FIG. 7

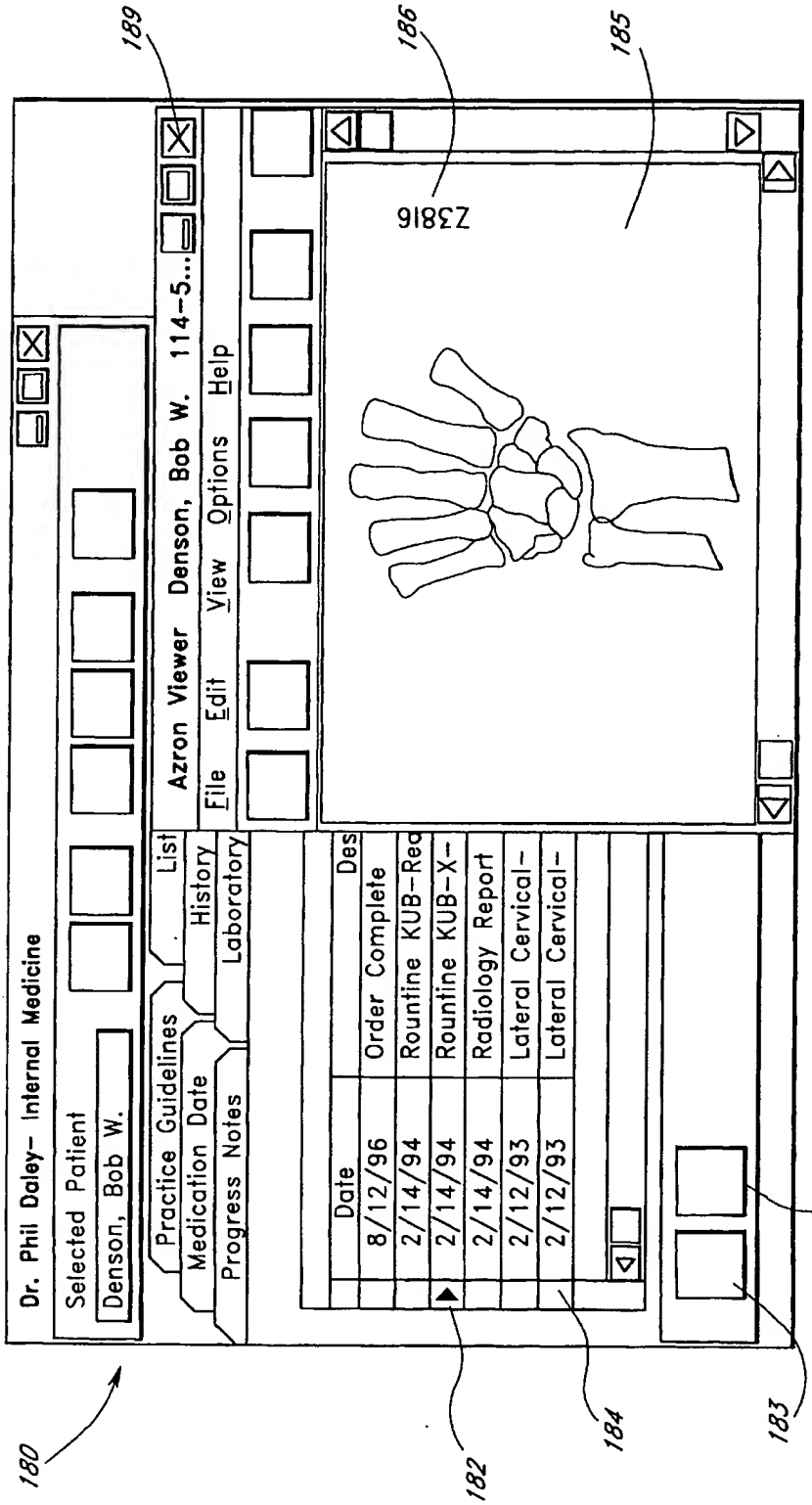

189
186
185
Z3816
Azron Viewer Denson, Bob W. 114-5...
File Edit View Options Help
Dr. Phil Daley- Internal Medicine
Selected Patient
Denson, Bob W.
Practice Guidelines
Medication Date
Progress Notes
List
History
Laboratory
Date
Des
8/12/96 Order Complete
2/14/94 Rountine KUB-Req
2/14/94 Rountine KUB-X-
2/14/94 Radiology Report
2/12/93 Lateral Cervical-
2/12/93 Lateral Cervical-
187
180
182
184
183

FIG. 8

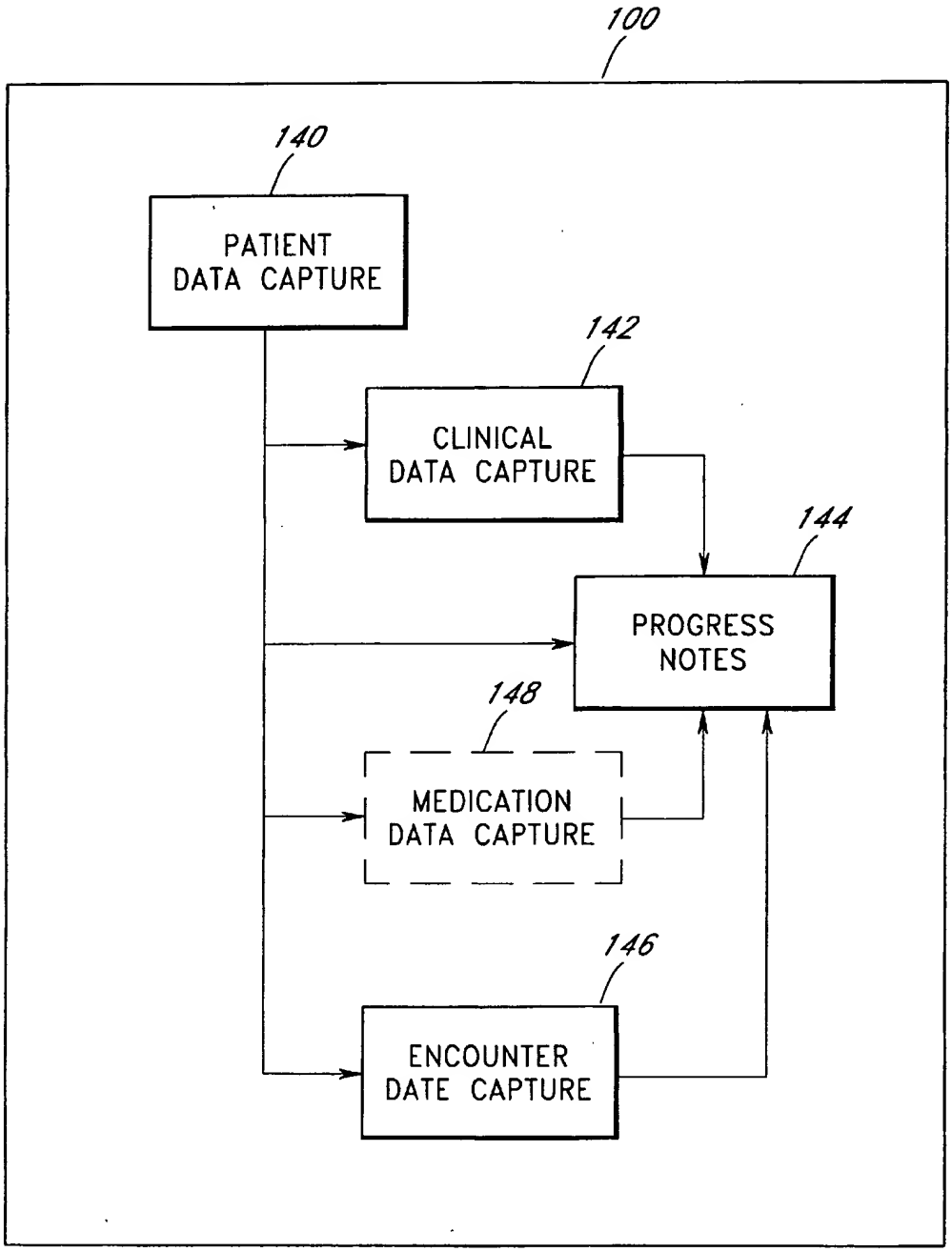

100
140
PATIENT DATA CAPTURE
142
CLINICAL DATA CAPTURE
144
PROGRESS NOTES
148
MEDICATION DATA CAPTURE
146
ENCOUNTER DATE CAPTURE

FIG. 9

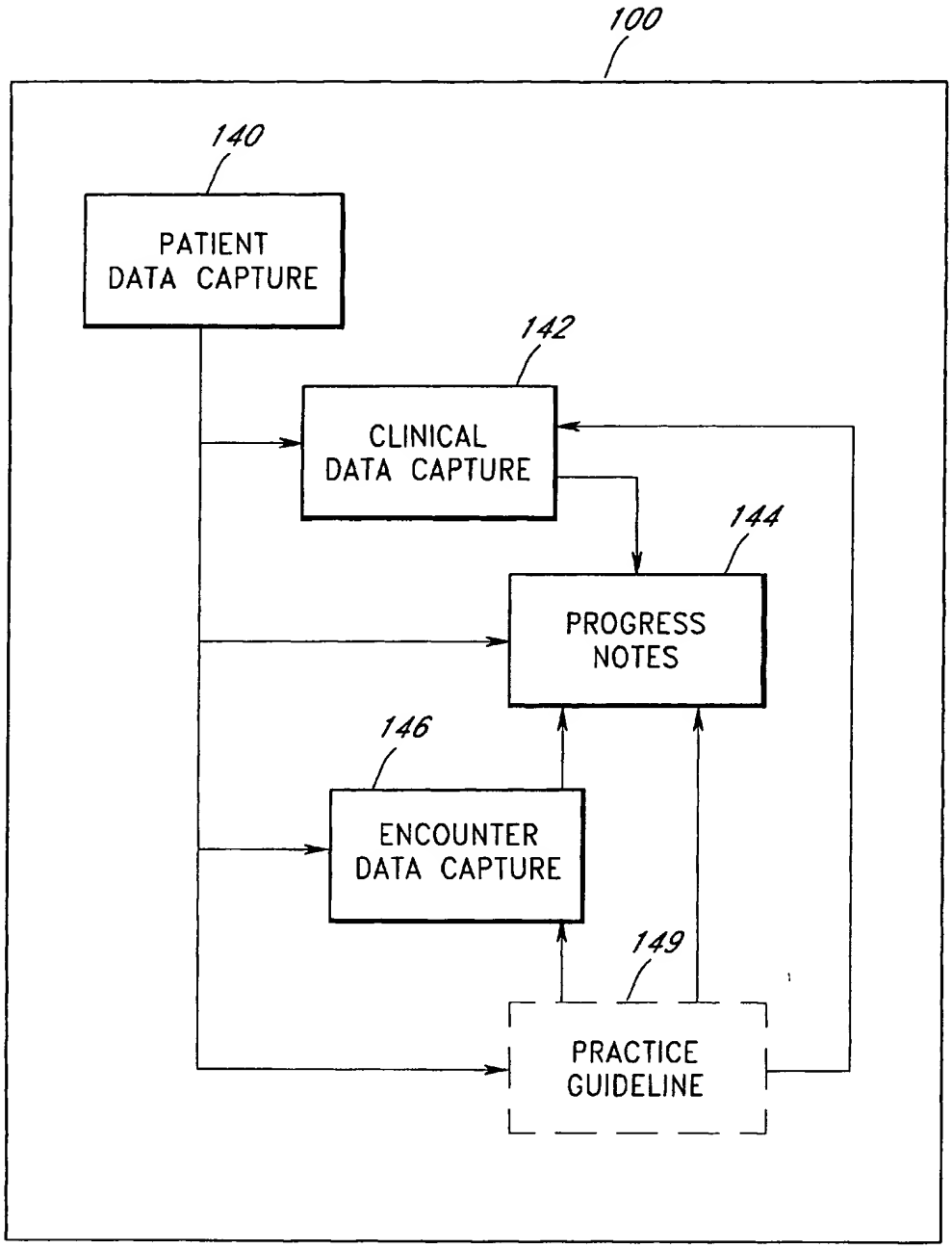

100
140
PATIENT DATA CAPTURE
142
CLINICAL DATA CAPTURE
144
PROGRESS NOTES
146
ENCOUNTER DATA CAPTURE
149
PRACTICE GUIDELINE

FIG. 10

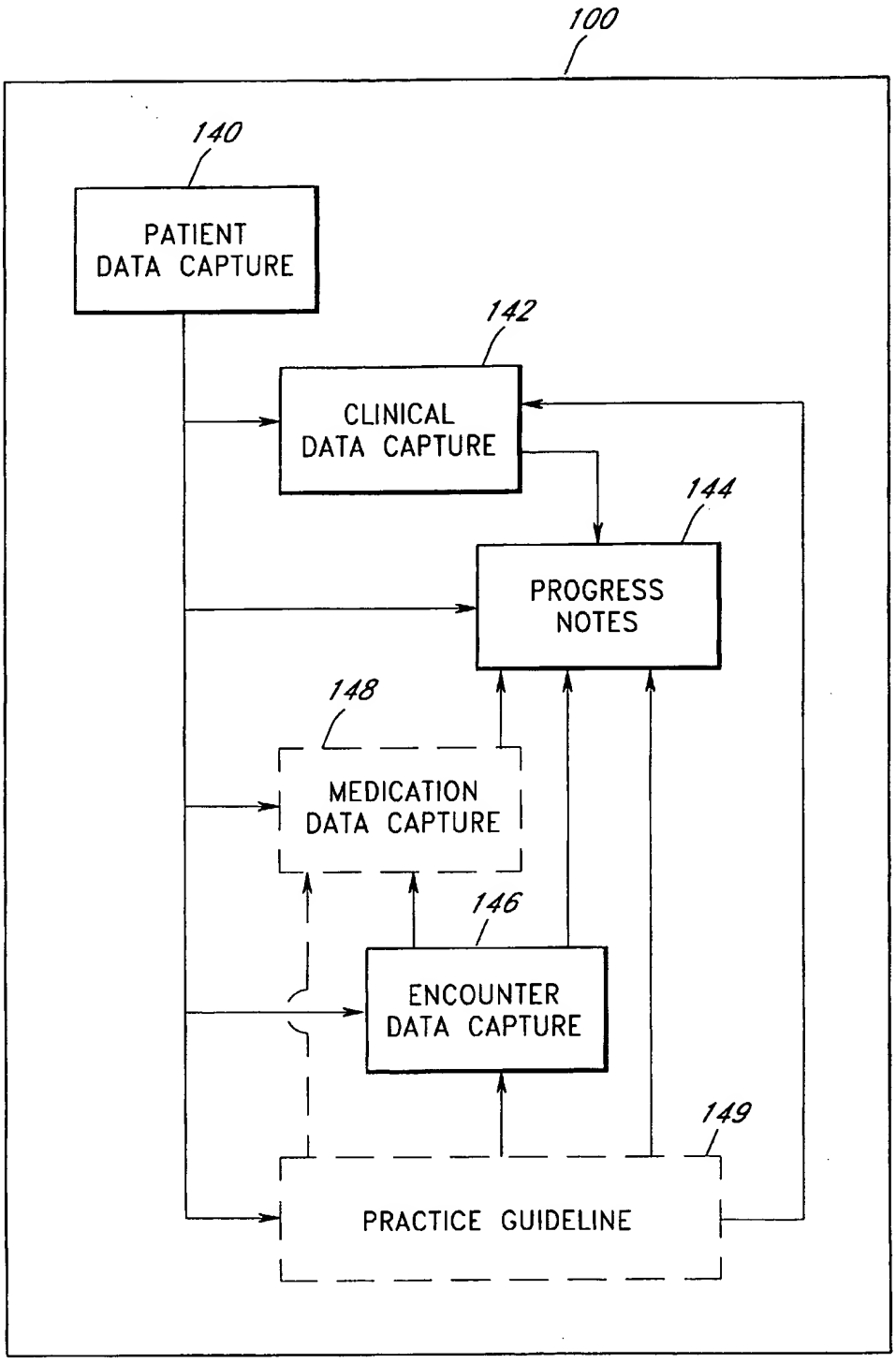

100
140
PATIENT DATA CAPTURE
142
CLINICAL DATA CAPTURE
144
PROGRESS NOTES
148
MEDICATION DATA CAPTURE
146
ENCOUNTER DATA CAPTURE
149
PRACTICE GUIDELINE

FIG. 11

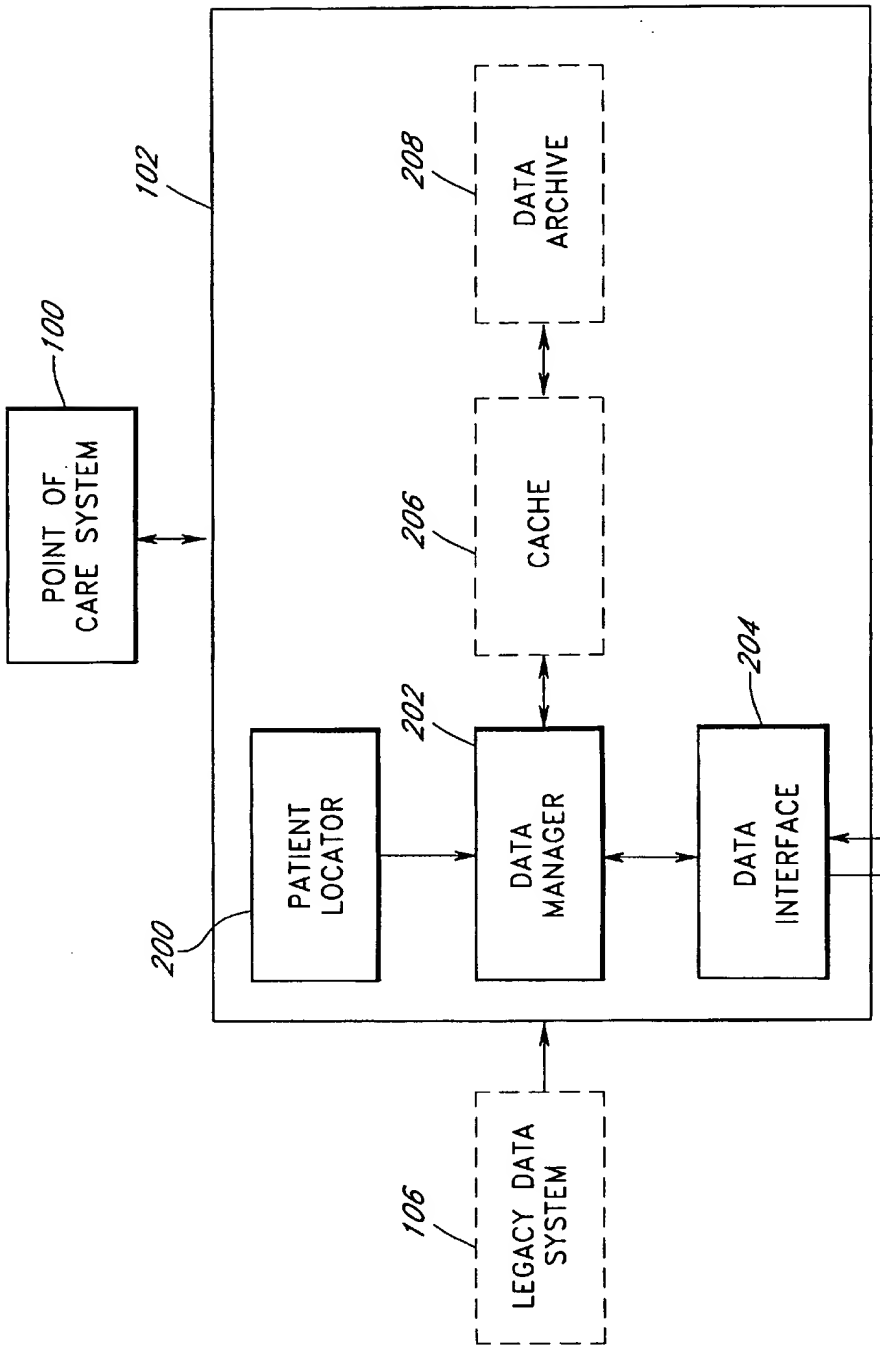

102
208
DATA ARCHIVE
100
POINT OF CARE SYSTEM
206
CACHE
202
204
PATIENT LOCATOR
DATA MANAGER
DATA INTERFACE
EXTERNAL DATA
200
106
LEGACY DATA SYSTEM

FIG. 12

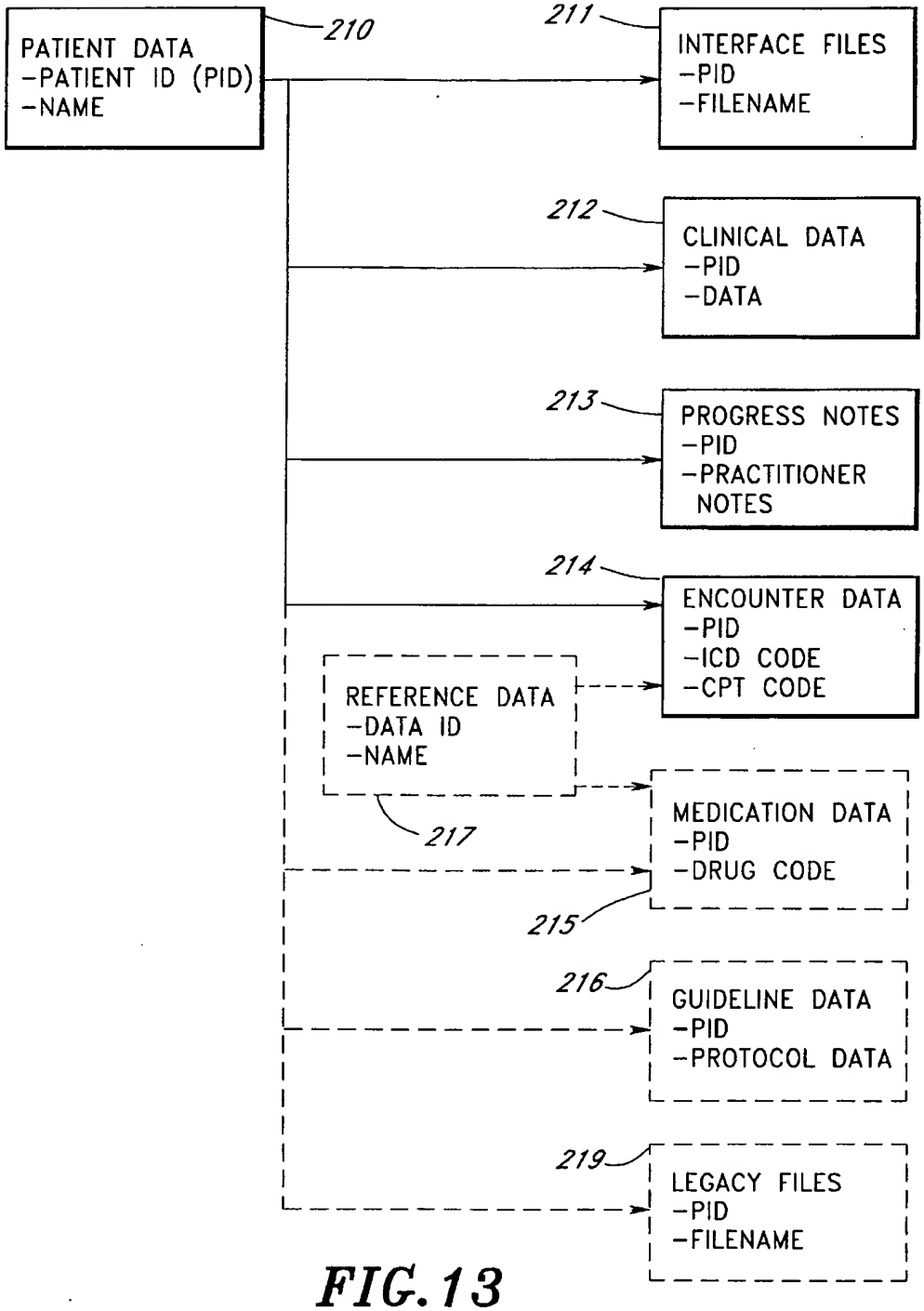

PATIENT DATA
-PATIENT ID (PID)
-NAME
210
211
INTERFACE FILES
-PID
-FILENAME
212
CLINICAL DATA
-PID
-DATA
213
PROGRESS NOTES
-PID
-PRACTITIONER NOTES
214
ENCOUNTER DATA
-PID
-ICD CODE
-CPT CODE
REFERENCE DATA
-DATA ID
-NAME
217
MEDICATION DATA
-PID
-DRUG CODE
215
216
GUIDELINE DATA
-PID
-PROTOCOL DATA
219
LEGACY FILES
-PID
-FILENAME

FIG. 13

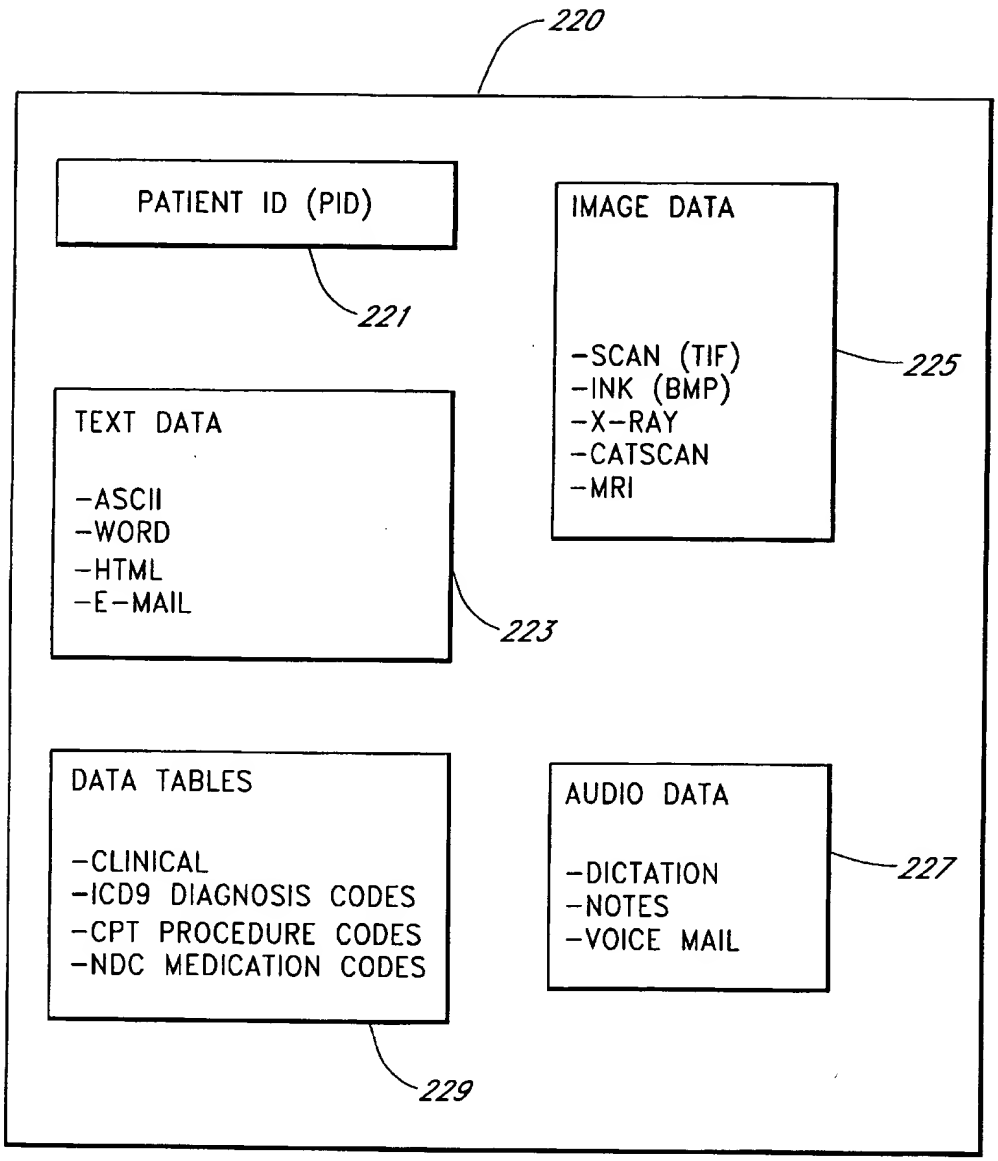

220
PATIENT ID (PID)
221
IMAGE DATA
-SCAN (TIF)
-INK (BMP)
-X-RAY
-CATSCAN
-MRI
225
TEXT DATA
-ASCII
-WORD
-HTML
-E-MAIL
223
DATA TABLES
-CLINICAL
-ICD9 DIAGNOSIS CODES
-CPT PROCEDURE CODES
-NDC MEDICATION CODES
229
AUDIO DATA
-DICTATION
-NOTES
-VOICE MAIL
227

FIG. 14

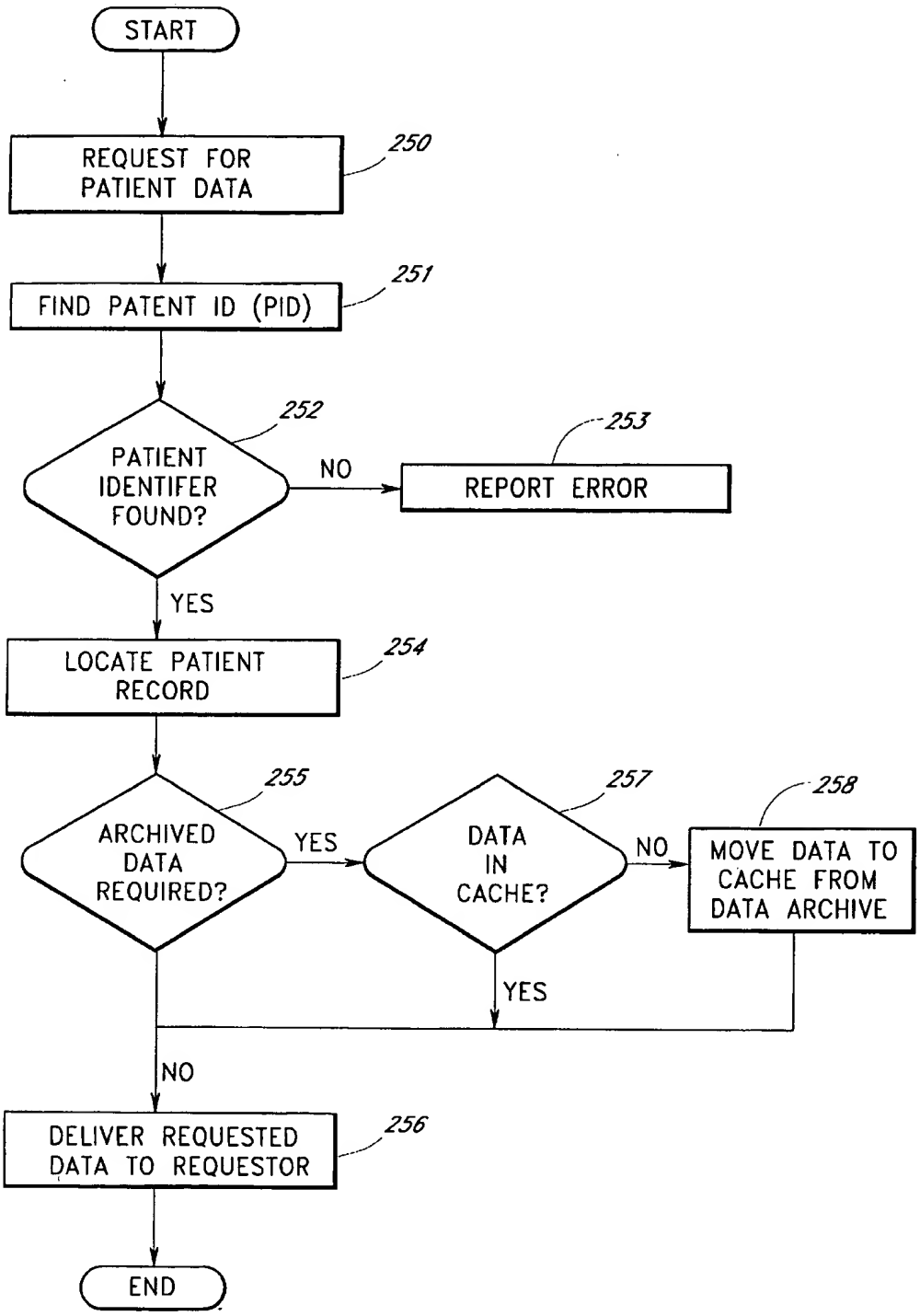

START
REQUEST FOR PATIENT DATA
250
FIND PATENT ID (PID)
251
PATIENT IDENTIFER FOUND?
252
NO
REPORT ERROR
253
YES
LOCATE PATIENT RECORD
254
ARCHIVED DATA REQUIRED?
255
YES
DATA IN CACHE?
257
NO
MOVE DATA TO CACHE FROM DATA ARCHIVE
258
YES
NO
DELIVER REQUESTED DATA TO REQUESTOR
256
END

FIG. 15A

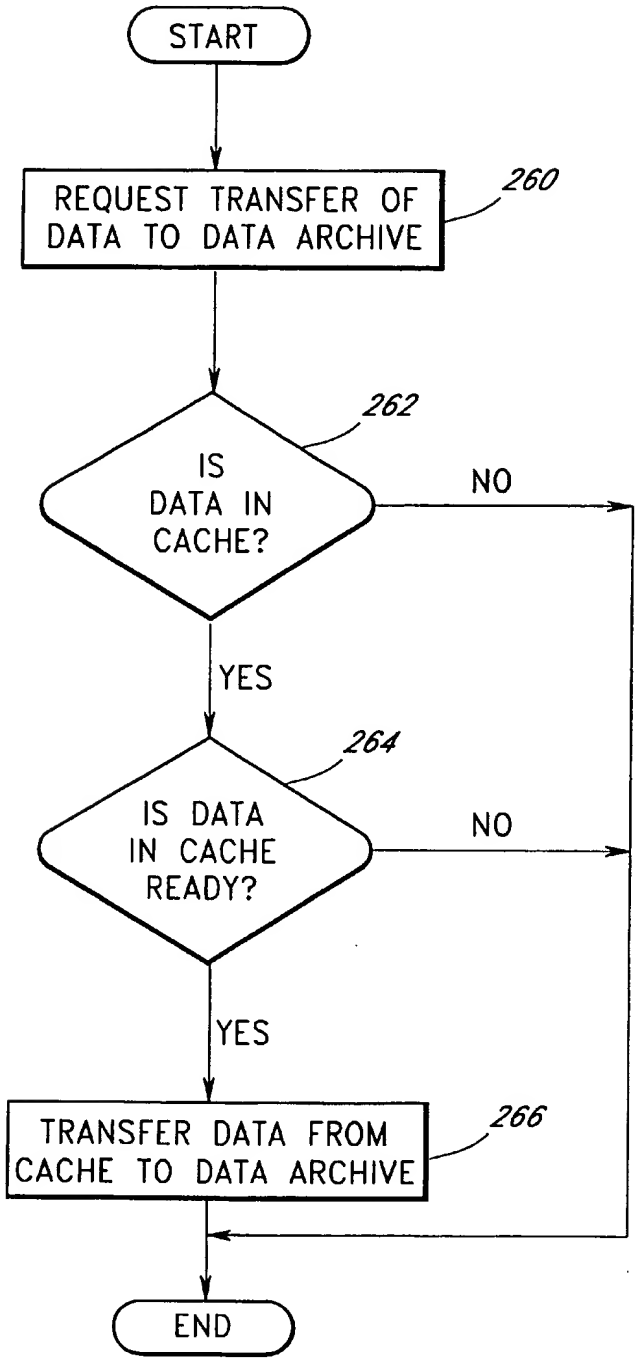

START
REQUEST TRANSFER OF DATA TO DATA ARCHIVE
260
IS DATA IN CACHE?
262
NO
YES
IS DATA IN CACHE READY?
264
NO
YES
TRANSFER DATA FROM CACHE TO DATA ARCHIVE
266
END

FIG. 15B

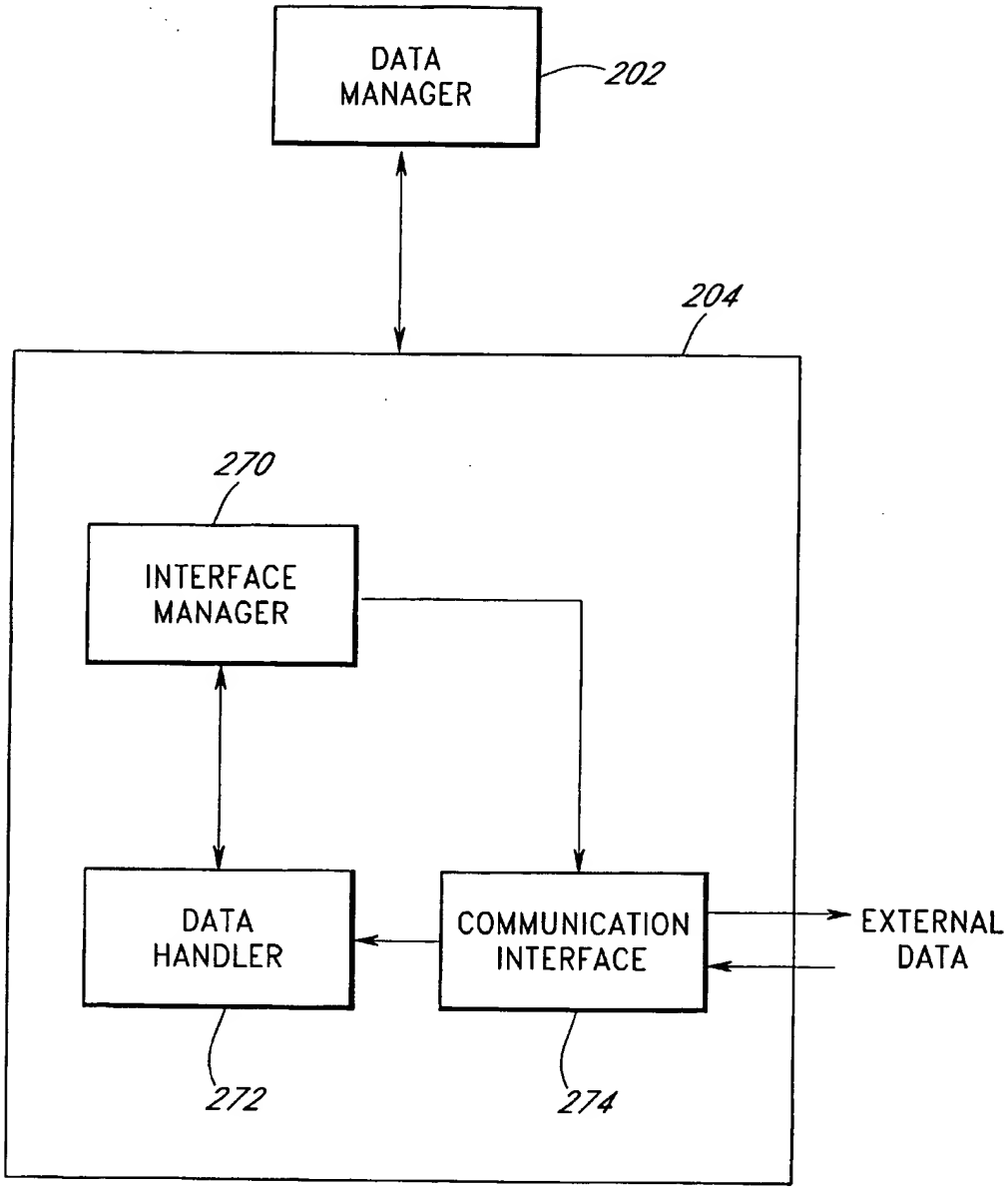

DATA MANAGER
202
204
270
INTERFACE MANAGER
DATA HANDLER
COMMUNICATION INTERFACE
EXTERNAL DATA
272
274

FIG. 16

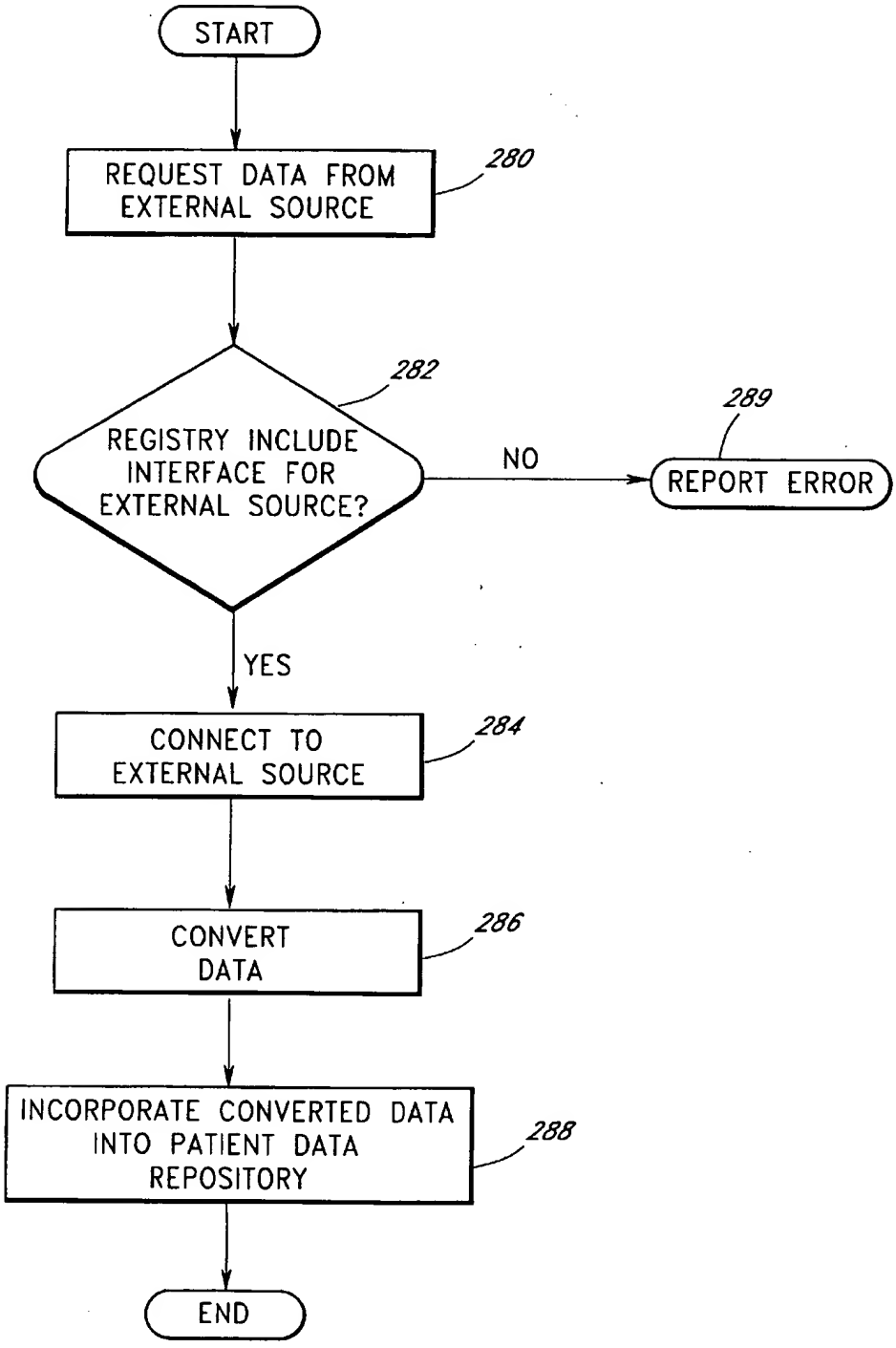

START
REQUEST DATA FROM EXTERNAL SOURCE
280
REGISTRY INCLUDE INTERFACE FOR EXTERNAL SOURCE?
282
NO
289
REPORT ERROR
YES
CONNECT TO EXTERNAL SOURCE
284
CONVERT DATA
286
INCORPORATE CONVERTED DATA INTO PATIENT DATA REPOSITORY
288
END

FIG. 17A

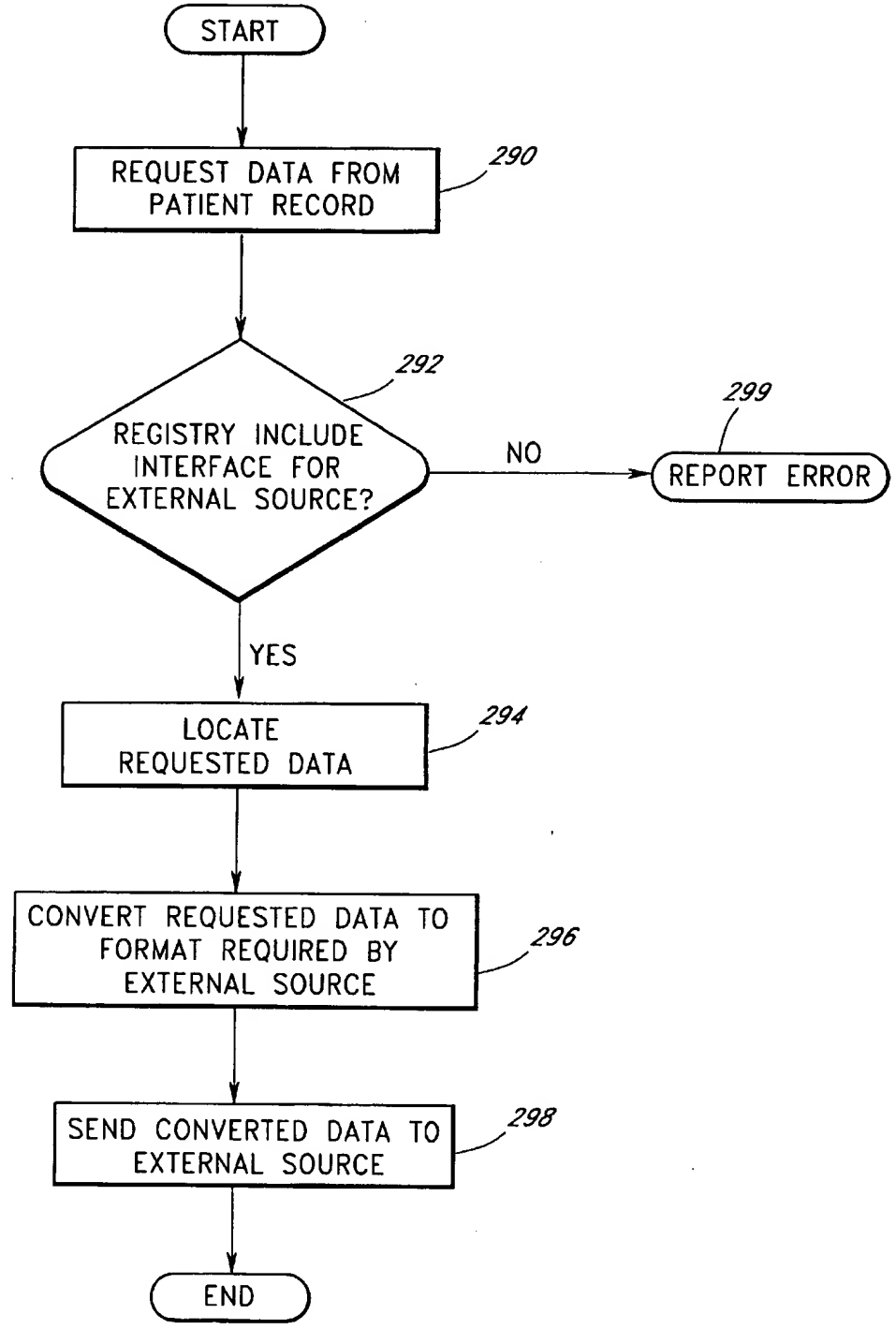

START
REQUEST DATA FROM PATIENT RECORD
290
REGISTRY INCLUDE INTERFACE FOR EXTERNAL SOURCE?
292
NO
299
REPORT ERROR
YES
LOCATE REQUESTED DATA
294
CONVERT REQUESTED DATA TO FORMAT REQUIRED BY EXTERNAL SOURCE
296
SEND CONVERTED DATA TO EXTERNAL SOURCE
298
END

FIG. 17B

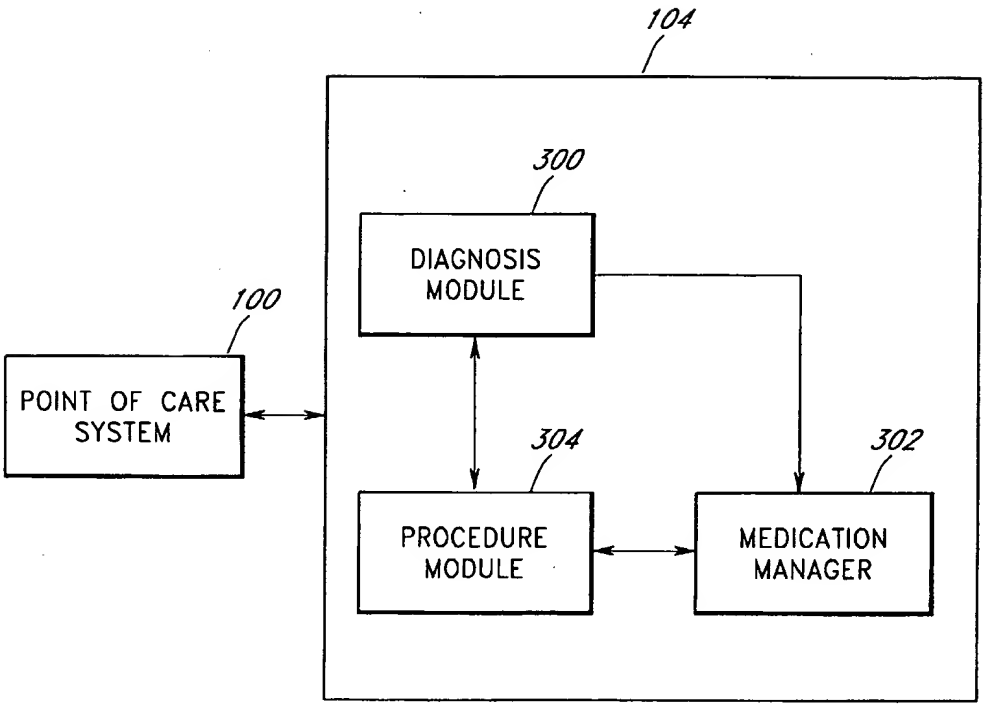

104
300
DIAGNOSIS MODULE
100
POINT OF CARE SYSTEM
304
302
PROCEDURE MODULE
MEDICATION MANAGER

FIG. 18

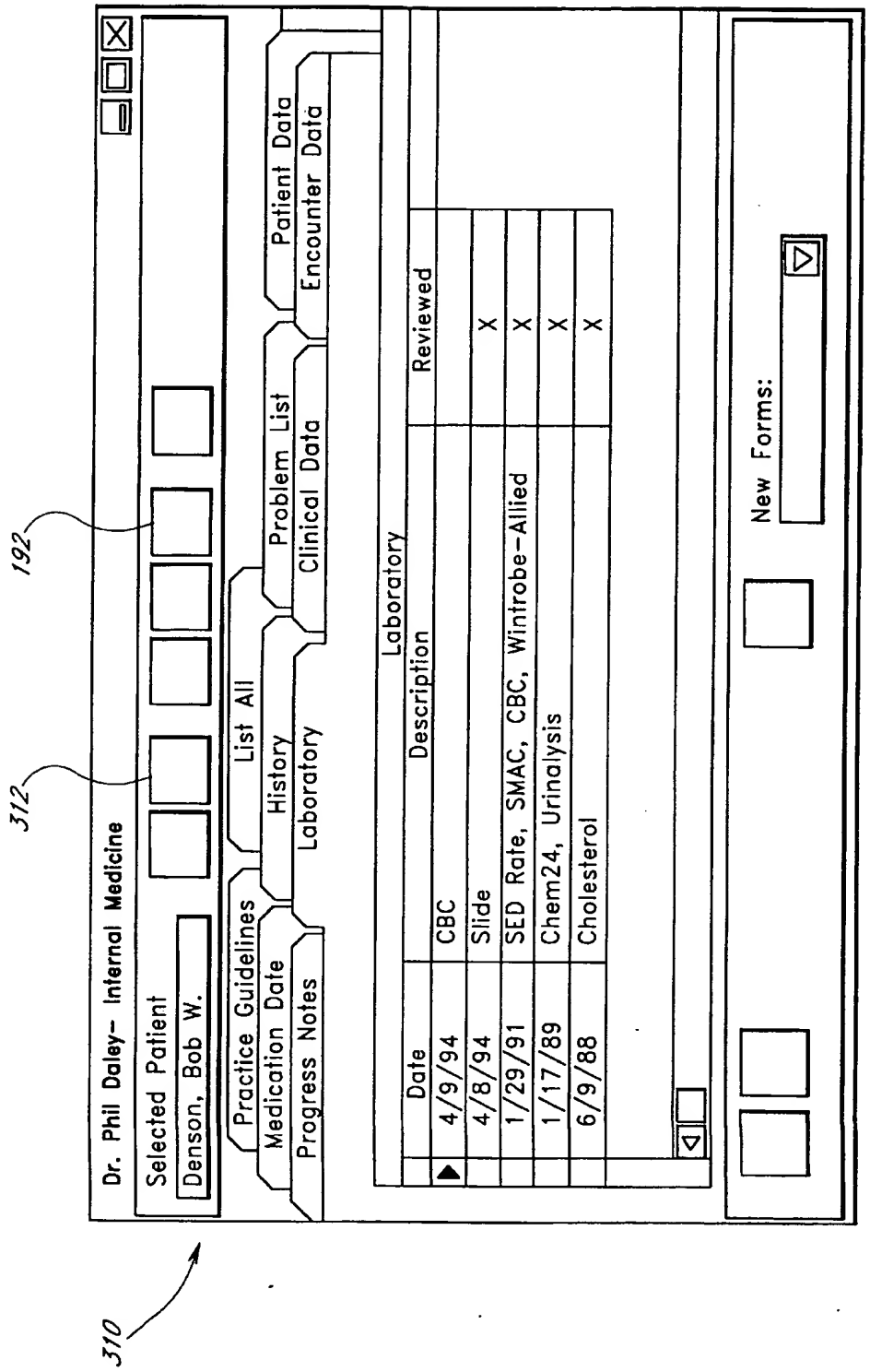

Dr. Phil Daley- Internal Medicine
Selected Patient
Denson, Bob W.
Practice Guidelines
Medication Date
Progress Notes
List All
History
Laboratory
Problem List
Clinical Data
Patient Data
Encounter Data
Laboratory
Date
Description
Reviewed
4/9/94
CBC
4/8/94
Slide
X
1/29/91
SED Rate, SMAC, CBC, Wintrobe-Allied
X
1/17/89
Chem24, Urinalysis
X
6/9/88
Cholesterol
X
New Forms:
192
312
310

FIG. 19

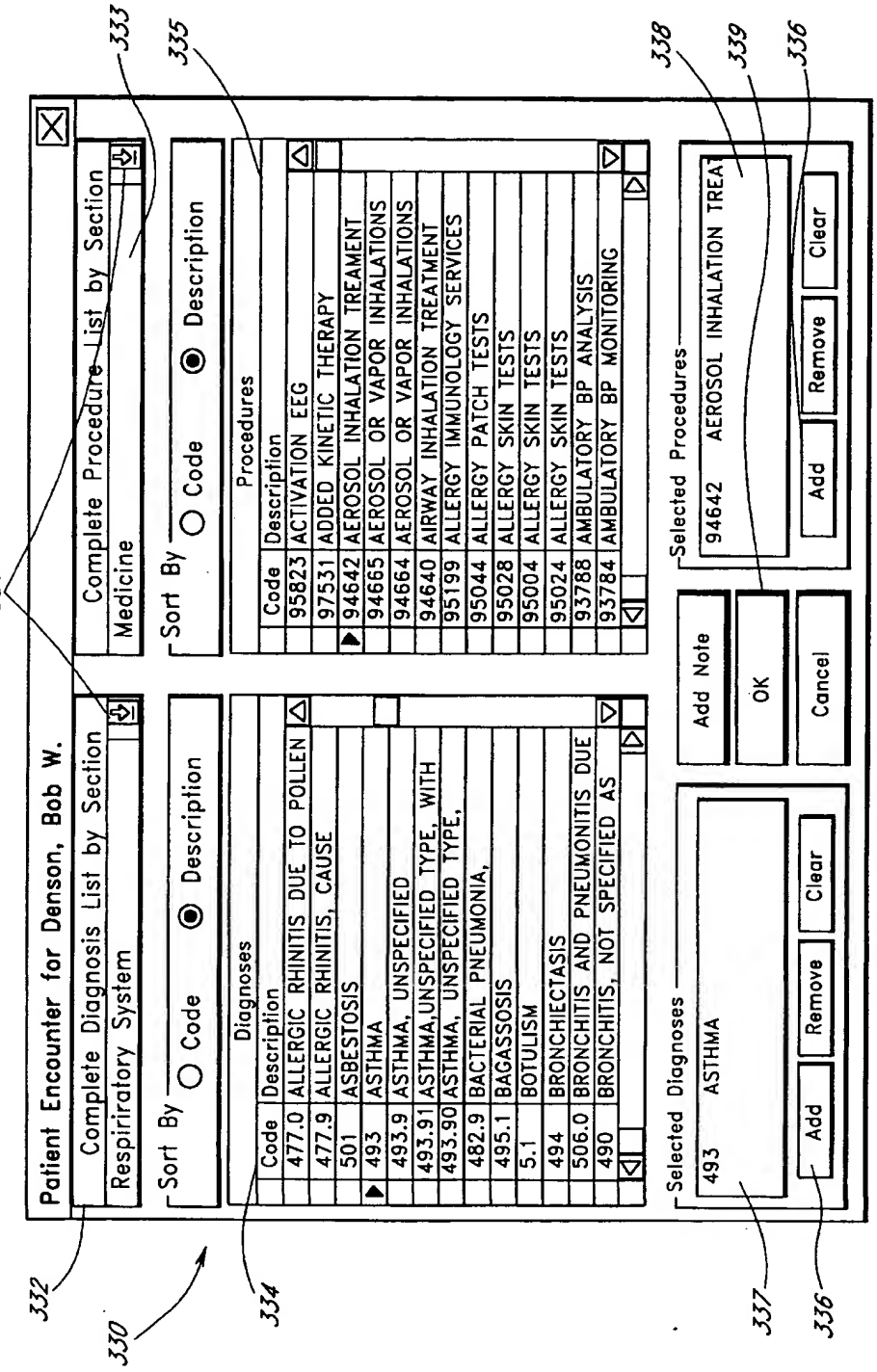

Patient Encounter for Denson, Bob W.
Complete Diagnosis List by Section
Respiriratory System
Complete Procedure List by Section
Medicine
Sort By
Code
Description
Diagnoses
Code
Description
477.0 ALLERGIC RHINITIS DUE TO POLLEN
477.9 ALLERGIC RHINITIS, CAUSE
501 ASBESTOSIS
493 ASTHMA
493.9 ASTHMA, UNSPECIFIED
493.91 ASTHMA,UNSPECIFIED TYPE, WITH
493.90 ASTHMA, UNSPECIFIED TYPE,
482.9 BACTERIAL PNEUMONIA,
495.1 BAGASSOSIS
5.1 BOTULISM
494 BRONCHIECTASIS
506.0 BRONCHITIS AND PNEUMONITIS DUE
490 BRONCHITIS, NOT SPECIFIED AS
Procedures
Code
Description
95823 ACTIVATION EEG
97531 ADDED KINETIC THERAPY
94642 AEROSOL INHALATION TREAMENT
94665 AEROSOL OR VAPOR INHALATIONS
94664 AEROSOL OR VAPOR INHALATIONS
94640 AIRWAY INHALATION TREATMENT
95199 ALLERGY IMMUNOLOGY SERVICES
95044 ALLERGY PATCH TESTS
95028 ALLERGY SKIN TESTS
95004 ALLERGY SKIN TESTS
95024 ALLERGY SKIN TESTS
93788 AMBULATORY BP ANALYSIS
93784 AMBULATORY BP MONITORING
Add Note
OK
Cancel
Selected Diagnoses
493 ASTHMA
Add
Remove
Clear
Selected Procedures
94642 AEROSOL INHALATION TREA
Add
Remove
Clear
331
332
333
334
335
336
337
338
339
330

FIG. 20

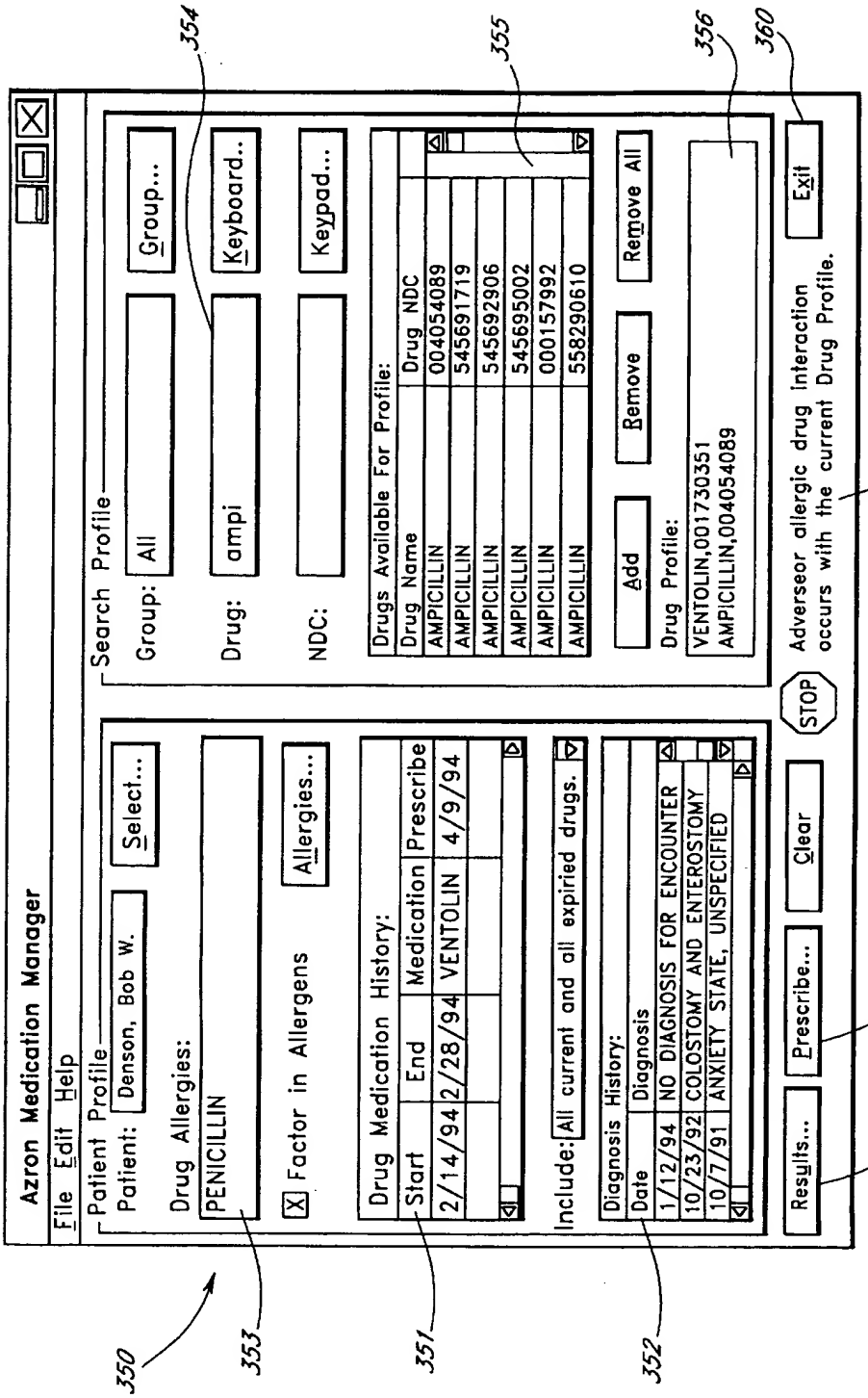

Azron Medication Manager
File Edit Help
Patient Profile
Patient: Denson, Bob W.
Select...
Drug Allergies:
PENICILLIN
X Factor in Allergens
Allergies...
Drug Medication History:
Start End Medication Prescribe
2/14/94 2/28/94 VENTOLIN 4/9/94
Include: All current and all expiried drugs.
Diagnosis History:
Date Diagnosis
1/12/94 NO DIAGNOSIS FOR ENCOUNTER
10/23/92 COLOSTOMY AND ENTEROSTOMY
10/7/91 ANXIETY STATE, UNSPECIFIED
Results...
Prescribe...
Clear
STOP
Search Profile
Group: All
Group...
Drug: ampi
Keyboard..
NDC:
Keypad...
Drugs Available For Profile:
Drug Name Drug NDC
AMPICILLIN 004054089
AMPICILLIN 545691719
AMPICILLIN 545692906
AMPICILLIN 545695002
AMPICILLIN 000157992
AMPICILLIN 558290610
Add
Remove
Remove All
Drug Profile:
VENTOLIN,001730351
AMPICILLIN,004054089
Adverseor allergic drug interaction occurs with the current Drug Profile.
Exit
350
353
351
352
354
355
356
360
357
359
358

FIG. 21

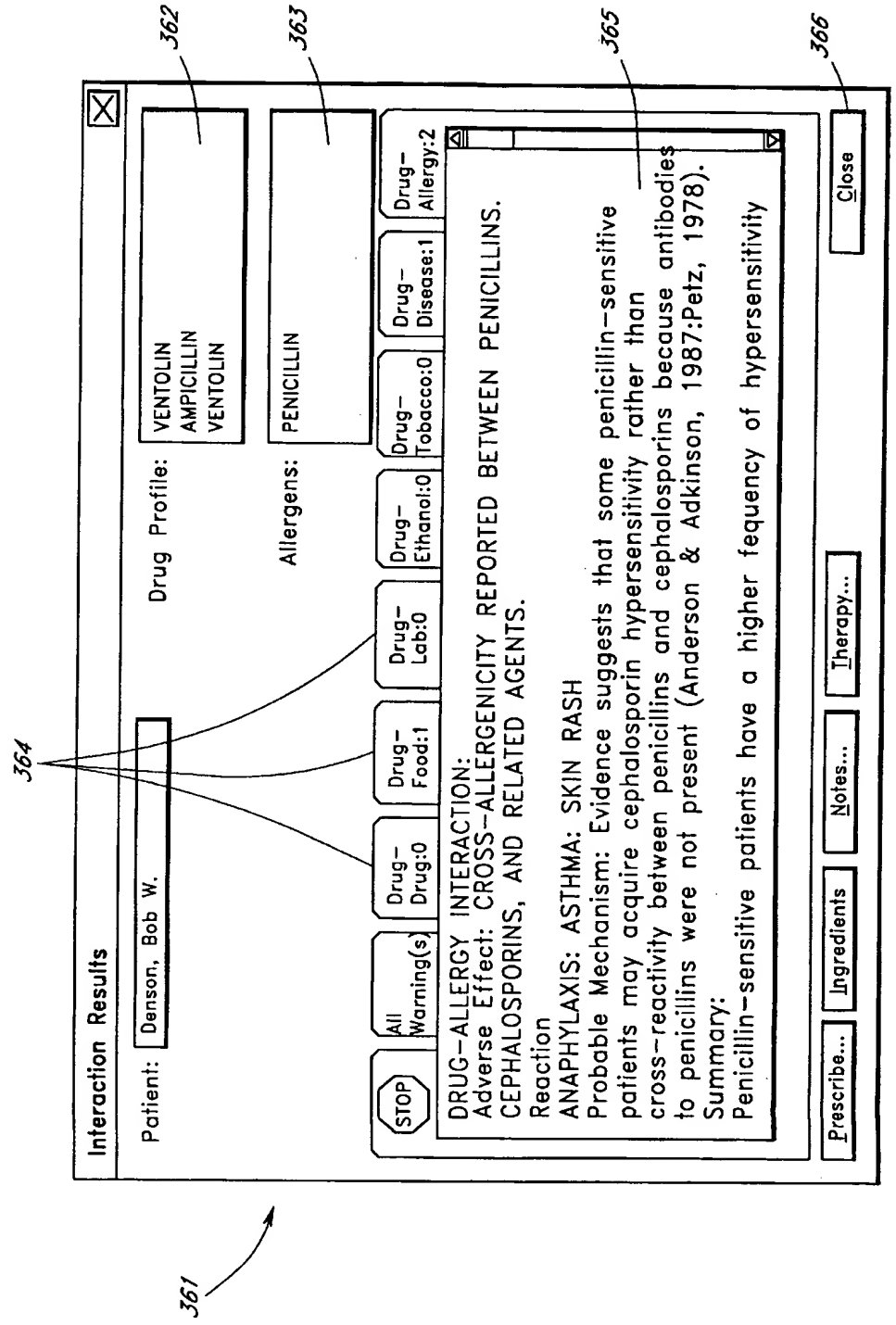

Interaction Results
Patient:
Denson, Bob W.
Drug Profile:
VENTOLIN
AMPICILLIN
VENTOLIN
Allergens:
PENICILLIN
STOP
All Warning(s)
Drug-Drug:0
Drug-Food:1
Drug-Lab:0
Drug-Ethanol:0
Drug-Tobacco:0
Drug-Disease:1
Drug-Allergy:2
DRUG-ALLERGY INTERACTION:
Adverse Effect: CROSS-ALLERGENICITY REPORTED BETWEEN PENICILLINS. CEPHALOSPORINS, AND RELATED AGENTS.
Reaction
ANAPHYLAXIS: ASTHMA: SKIN RASH
Probable Mechanism: Evidence suggests that some penicillin-sensitive patients may acquire cephalosporin hypersensitivity rather than cross-reactivity between penicillins and cephalosporins because antibodies to penicillins were not present (Anderson & Adkinson, 1987:Petz, 1978).
Summary:
Penicillin-sensitive patients have a higher fequency of hypersensitivity
Prescribe...
Ingredients
Notes...
Therapy...
Close
361
362
363
364
365
366

FIG.22

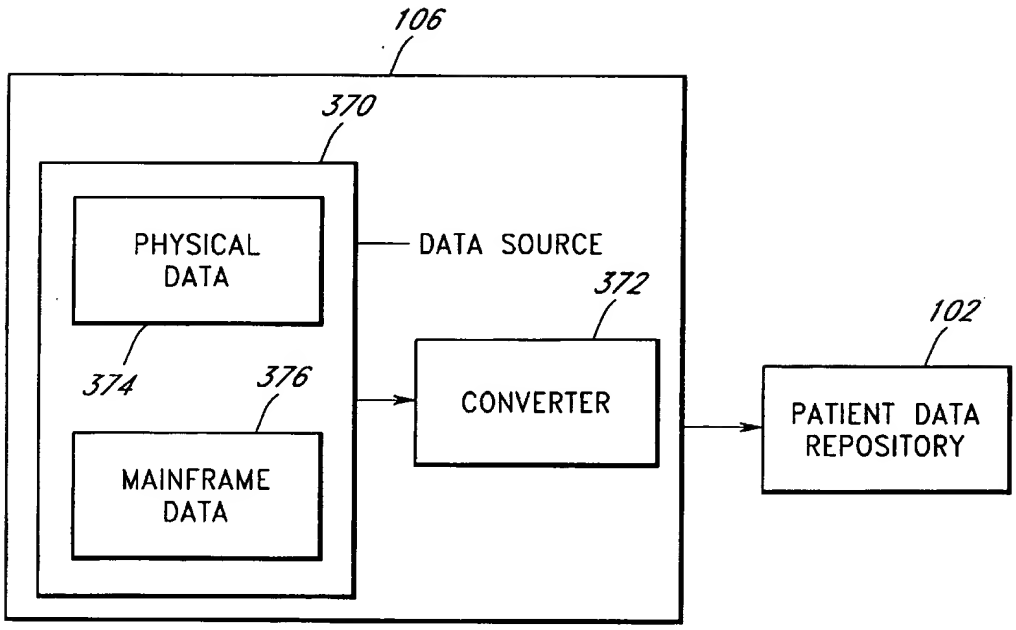

106
370
PHYSICAL DATA
DATA SOURCE
372
102
374
376
CONVERTER
PATIENT DATA REPOSITORY
MAINFRAME DATA

FIG. 23

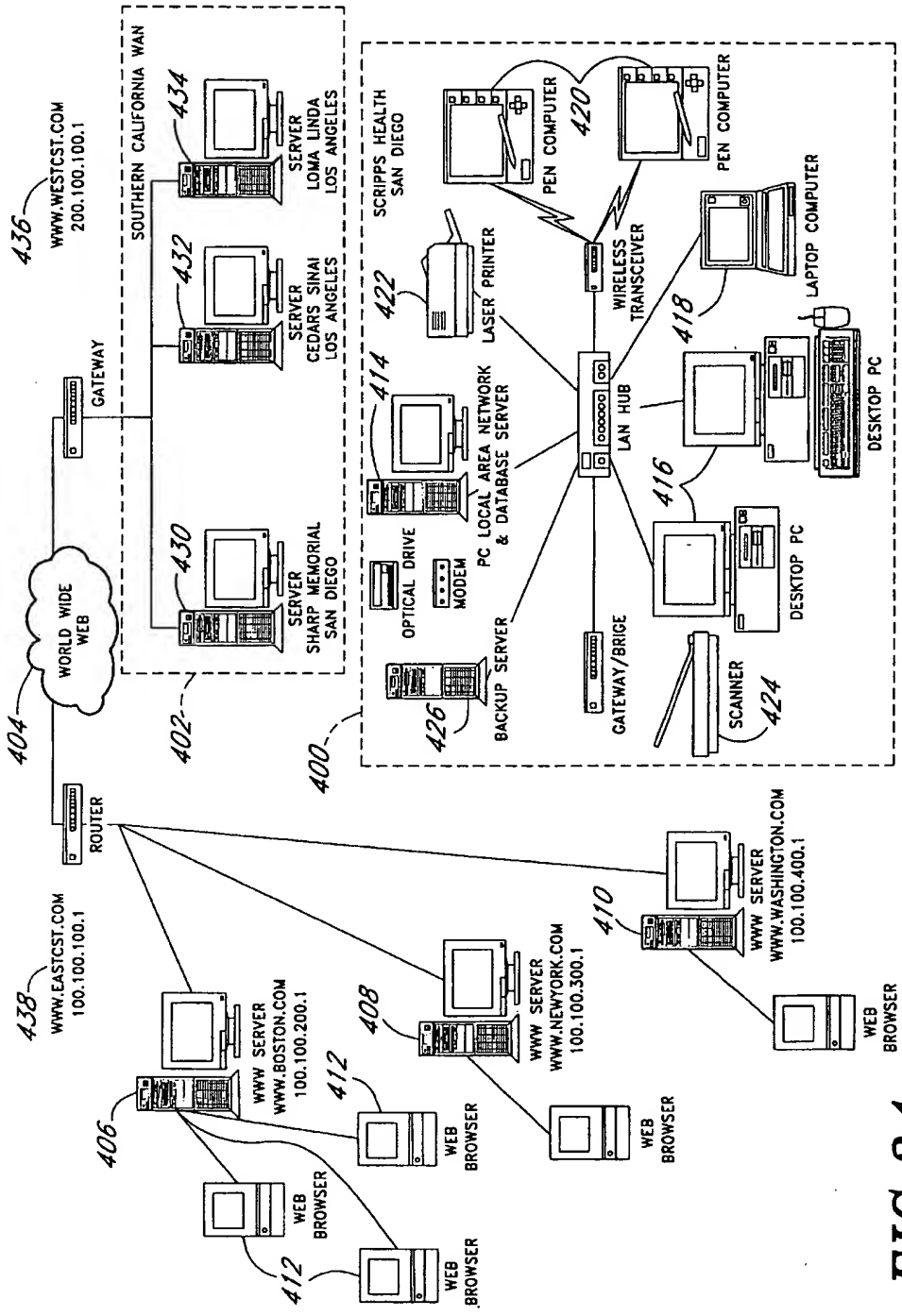

WWW.WESTCST.COM
200.100.100.1
436
SOUTHERN CALIFORNIA WAN
SERVER
LOMA LINDA
LOS ANGELES
434
SERVER
CEDARS SINAI
LOS ANGELES
432
SERVER
SHARP MEMORIAL
SAN DIEGO
430
GATEWAY
WORLD WIDE
WEB
404
402
SCRIPPS HEALTH
SAN DIEGO
400
PEN COMPUTER
420
PEN COMPUTER
WIRELESS
TRANSCEIVER
LASER PRINTER
422
LAPTOP COMPUTER
418
LAN HUB
PC LOCAL AREA NETWORK
& DATABASE SERVER
414
OPTICAL DRIVE
MODEM
DESKTOP PC
416
BACKUP SERVER
426
GATEWAY/BRIGE
SCANNER
424
DESKTOP PC
ROUTER
WWW.EASTCST.COM
100.100.100.1
438
WWW SERVER
WWW.WASHINGTON.COM
100.100.400.1
410
WWW SERVER
WWW.BOSTON.COM
100.100.200.1
406
WWW SERVER
WWW.NEWYORK.COM
100.100.300.1
408
WEB
BROWSER
412
WEB
BROWSER
WEB
BROWSER
WEB
BROWSER
412
WEB
BROWSER

FIG.24

ELECTRONIC MEDICAL RECORDS SYSTEM

FIELD OF THE INVENTION

The present invention relates to electronic healthcare systems, and more particularly, to a system for storage and retrieval of electronic medical records in a computer environment, such as a local or wide area network including portable computers.

DESCRIPTION OF RELATED TECHNOLOGY

Healthcare providers, such as physicians, create large volumes of patient information during the course of their business at healthcare facilities, such as hospitals, clinics, laboratories and medical offices. For example, when a patient visits a physician for the first time, the physician generally creates a patient file including the patient's medical history, current treatments, medications, insurance and other pertinent information. This file generally includes the results of patient visits, including laboratory test results, the physician's diagnosis, medications prescribed and treatments administered. During the course of the patient relationship, the physician supplements the file to update the patient's medical history. When the physician refers a patient for treatment, tests or consultation, the referred physician, hospital, clinic or laboratory typically creates and updates similar files for the patient. These files may also include the patient's billing, payment and scheduling records.

Healthcare providers can use electronic data processing to automate the creation, use and maintenance of their patient records. For example, in U.S. Pat. No. 5,277,188, assigned to New England Medical Center Hospitals, Inc., Selker discloses a clinical information reporting system having an electronic database including electrocardiograph related patient data. Similarly, Schneiderman discloses a computer system for recording electrocardiograph and/or chest x-ray test results for a database of patients in U.S. Pat. No. 5,099,424. In U.S. Pat. No. 4,315,309, Coli discloses a patient report generating system for receiving, storing and reporting medical test data for a patient population. Mitchell, in U.S. Pat. No. 3,872,448, likewise discloses a system for automatically handling and processing hospital data, such as patient information and pathological test information using a central processing apparatus. In U.S. Pat. No. 5,065,315, Garcia discloses a computerized scheduling and reporting system for managing information pertinent to a patient's stay in the hospital. However, these electronic data processing systems can not handle patient data in the wide variety of data formats typically produced by healthcare providers, such as physicians, laboratories, clinics and hospitals.

Physicians often use paper based forms and charts to document their observations and diagnosis. Laboratories also produce patient data in numerous forms, from x-ray and magnetic resonance images to blood test concentrations and electrocardiograph data. Clinics and hospitals may use a combination of paper based charts and electronic data for patient records. The same patient data may exist in remote patient files located at clinics, hospitals, laboratories and physicians'offices. Similarly, patient files at one healthcare provider typically have different information than patient files at another healthcare provider. When in use, patient files are generally not available to other healthcare providers. In addition, at the time of creation, patient data is generally not available for use by remotely located healthcare providers. Moreover, relationships among specific patient data, such as abnormal laboratory test results, prescribed medications to address the abnormality, and specific treatments administered by the physician, may not be apparent within a patient file.

In the current environment, specific patient data is difficult to access when needed for analysis. The creation of patient data in remote locations exacerbates this problem. In addition, the wide variety of data formats for patient data hinders electronic processing and maintenance of patient files. Moreover, the use of a patient's file by one healthcare provider can preclude its simultaneous use by another healthcare provider. Ongoing consolidation of healthcare providers into large health maintenance organizations (HMOs) and preferred provider organizations (PPOs) create issues in the transfer and maintenance of patient data in large enterprises having numerous remote locations. Under these circumstances, healthcare providers have difficulty providing effective treatment for their patients.

SUMMARY OF THE INVENTION

The electronic medical record (EMR) system of the present invention automates and simplifies existing methods of patient chart creation, maintenance and retrieval. In contrast to other systems, the present invention creates and maintains all patient data electronically and thus can eliminate or supplement creating and maintaining of physical data records. The EMR system finishes healthcare providers with an intuitive, easy-to-use, icon-based interface that enables them to capture and analyze patient data quickly and efficiently. Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry to provide a complete audit trail for all patient data. In this manner, the EMR system transforms a patient chart from a static record of a few clinical interactions into a dynamic, real-time comprehensive record linked to an enterprise-wide clinical database. In addition, the EMR system of the present invention includes the capability to manage a wide variety of patient data formats, including patient data from external sources, such as laboratories and pharmacies. The EMR system can also incorporate a patient's legacy data, such as a paper chart, into the patient record as well as legacy data from mainframe computers.

The present invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables authorized healthcare providers to access and update patient files using wireless pen-based personal computers. To enable complete replacement of physical records, the present invention permits healthcare providers, such as physicians or nurse practitioners, to electronically annotate patient data. Thus, a healthcare provider can acknowledge reviewing patient data, provide instructions, such as prescriptions for medication to administer to a patient, and approve recommendations for treatment by other providers, all by electronically annotating a patient's record. In addition, authorized healthcare providers can access a record while other providers use the same record allowing for real-time collaboration. The availability of electronic data permits instant, sophisticated analysis of patient data. Moreover, the EMR system enables enhanced analysis of patient data by providing access to reference databases for diagnosis, procedures and medication.

One aspect of the present invention includes a medical records system, comprising a point of care system to capture patient data at a point of care and a patient data repository,

in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

Another aspect of the present invention includes a medical records system comprising a point of care system to capture data in a patient record at a point of care, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

Yet another aspect of the present invention includes a medical records system comprising a point of care system to capture data at a point of care and a patient data repository, in communication with the point of care system and with external systems to store and organize the data in a patient record for access by the point of care system, wherein the patient record includes a patient identifier and at least one data structure including the patient identifier and the data.

In addition, another aspect of the present invention includes a method of using an electronic medical records system, comprising the steps of capturing patient data electronically at the point of care, organizing the patient data so as to form a patient record, filing the patient record, and retrieving the patient record to access the patient data for use in the care of a patient.

Yet another aspect of the present invention includes a method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of obtaining a patient identifier, locating a patient record corresponding to the patient identifier in the patient data repository, and determining the location of the patient data within the patient record.

Another aspect of the present invention includes a method of managing a patient data repository having a cache and a data archive, comprising the steps of monitoring a status of data within the cache, and moving the data to the data archive when the status exceeds a threshold.

Still another aspect of the present invention includes a method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of finding an interface for the external source, connecting to the external source using the interface, and converting patient data for transfer between the external source and the electronic medical records system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating the electronic medical record (EMR) system architecture of the present invention.

FIG. **2** is a flowchart illustrating the process flow of the EMR system of the present invention.

FIG. **3** shows an example of a graphical user interface of the EMR system useful for the scheduling of a patient appointment as shown in FIG. **2**.

FIG. **4** is a block diagram illustrating the structure of the point of care system of FIG. **1**.

FIG. **5** shows an example of a graphical user interface of the point of care system of FIG. **4**.

FIG. **6** shows an example of a new form window of the point of care system of FIG. **4**.

FIG. **7** shows an example of an annotate window of the point of care system of FIG. **4**.

FIG. **8** shows an example of a viewer window displaying an image of patient data of the point of care system of FIG. **4**.

FIG. **9** is a block diagram illustrating the structure of a medication data capture in the point of care system of FIG. **4**.

FIG. **10** is a block diagram illustrating the structure of a practice guideline in the point of care system of FIG. **4**.

FIG. **11** is a block diagram illustrating the structure of the medication data capture and the practice guideline in the point of care system of FIG. **4**.

FIG. **12** is a block diagram illustrating the structure of the patient data repository of FIG. **1**.

FIG. **13** is a block diagram illustrating the structure of a patient record within the patient data repository of FIG. **12**.

FIG. **14** is an example of the patient record of FIG. **13**.

FIG. **15***a* is a flowchart illustrating the process flow of the patient data repository of FIG. **12**.

FIG. **15***b* is a flowchart illustrating the process for a transfer of data from a cache to a data archive in the patient data repository of FIG. **12**.

FIG. **16** is a block diagram illustrating the structure of the data interface of FIG. **12**.

FIG. **17***a* is a flowchart illustrating the process flow of the data interface of FIG. **16** when receiving patient data from an external source.

FIG. **17***b* is a flowchart illustrating the process flow of the data interface of FIG. **16** when transmitting patient data to an external source.

FIG. **18** is a block diagram illustrating the structure of the reference database of FIG. **1**.

FIG. **19** shows an example of a graphical user interface of the point of care system of FIG. **4** having a reference access button and a medication manager button.

FIG. **20** shows an example of a graphical user interface for the diagnosis module and the procedure module of the reference database of FIG. **18**.

FIG. **21** shows an example of a graphical user interface for the medication manager of the reference database of FIG. **18**.

FIG. **22** shows an example of a medication interaction window of the medication manager of FIG. **21**.

FIG. **23** is a block diagram illustrating the structure of the legacy data system of FIG. **1**.

FIG. **24** is an example of a typical configuration for the electronic medical records system of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description of the preferred embodiments presents a description of certain specific embodiments to assist in understanding the claims. However, one may practice the present invention in a multitude of different embodiments as defined and covered by the claims.

For convenience, the description comprises three sections: EMR System Architecture and Overview, EMR System Configurations and Summary. The first section provides an overview of the EMR system architecture, the following section describes EMR system applications and preferred embodiments for practicing the EMR system of the present invention, and the remaining section summarizes advantageous features of the present invention.

I. EMR System Architecture and Overview

FIG. **1** illustrates the architecture of the EMR system. Healthcare providers, such as physicians, at hospitals, laboratories and clinics, generally capture and access patient data using a point of care system **100** that communicates with a

patient data repository **102**. Patient data, such as vital signs, x-ray images and laboratory results, resides in the patient data repository **102**. The patient data repository **102** also communicates with external sources to obtain patient data, such as laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the EMR system to other healthcare providers. The point of care system **100** captures patient data in real-time at the point of care, that is, where healthcare providers interact with their patients. For example, physicians can use a point of care system **100** to enter, access, process, analyze and annotate data from patient records in real-time at the point of care. Thus, using the point of care system **100**, a physician, who has many patients in a hospital, can visit each patient in their room, access their electronic patient record there, enter results of the current examination, evaluate their medical history, electronically annotate their x-rays images and prescribe medications and treatments instantaneously as the point of care system **100** captures and organizes patient data into the patient record stored in the patient data repository **102**. The point of care system **100** may likewise communicate with a reference database **104** to assist a healthcare provider in making diagnoses, prescribing medications and administering treatments. Moreover, the patient data repository **102** may also communicate with a legacy data system **106** to access pertinent patient data in paper files and mainframe electronic databases.

Referring now to FIG. **2**, a flowchart illustrates the operation of the EMR system. For example, a patient having a complaint contacts a healthcare provider **110**, such as a physician, to schedule an appointment. The EMR system obtains the patient record **111** from the patient data repository **102** (FIG. **1**) prior to the scheduled appointment. The EMR system is also capable of handling patients on a walk-in basis by scheduling an appointment and requesting the patient's record immediately thereafter. The EMR system updates the patient record **112** to include the complaint and other information pertinent to the appointment, such as insurance information. A healthcare provider, such as a physician, examines the patient **113** using the point of care system **100** (FIG. **1**) to make a diagnosis and to treat the patient's condition. As determined at **114**, if a diagnosis is not possible on the basis of this examination, the physician may need to obtain additional clinical data **115**, such as laboratory tests and x-rays. When available, the physician uses the point of care system **100** (FIG. **1**) to evaluate the results **116** and to examine the patient **113** again in light of the results. Upon making a diagnosis, the physician may need to prescribe medications **117** for the patient's condition. Similarly, the physician may need to administer a treatment **118** to address the patient's condition. At the conclusion of the patient's visit, the EMR system files the patient's record **119** in the patient data repository **102** (FIG. **1**) for future reference.

In a preferred embodiment, the EMR system includes graphical user interfaces to access system functions. For example, as shown in FIG. **3**, a chart puller window **120** enables a healthcare provider to schedule a patient appointment using its point and click interface. To schedule an appointment, a healthcare provider activates the select button **121** with a pointing device, such as a mouse or electronic pen, to obtain a list of patients. The healthcare provider then scans the list to select the name of the appropriate patient using a pointing device. The EMR system places the name of the selected patient in the patient box **123**. Similarly, the healthcare provider uses the up/down buttons **125** to select an appointment date and an appointment time. An adjacent box, such as the date box **126**, displays the selected date and time. Lastly, the healthcare provider enters a textual description of the patient's complaint in a reason box **127**. Note that the healthcare provider can review prior or future scheduled appointments by clicking on the appointments button **128**. Similarly, the healthcare provider can track referrals by entering the identity of persons who referred this patient to their care in the referral box **129**.

Referring now to FIG. **4**, a block diagram illustrates the structure of the point of care system **100**. The point of care system **100** includes the following modules: a patient data capture **140**, a clinical data capture **142**, progress notes **144** and an encounter data capture **146**. During a patient visit, the healthcare provider (not shown) can enter, review and annotate patient information, such as family history, appointments, current medications and complaints, using the patient data capture **140**. The healthcare provider can likewise enter, review and annotate clinical data obtained during the visit, such as body temperature and blood pressure, using the clinical data capture **142**. Similarly, the healthcare provider can enter laboratory data for patients with the clinical data capture **142**. The clinical data capture **142** communicates with the patient data capture **140** to assist in identifying needs for further clinical data. For example, a family history of high blood pressure may indicate a need to obtain the patient's blood pressure during the visit. The patient data capture **140** also communicates with the encounter data capture **146**, where a healthcare provider can enter, review and annotate data regarding diagnoses and procedures administered to the patient. Moreover, the healthcare provider can use the progress notes **144** to summarize details of the patient's condition and to review the patient's progress over time. Thus, the progress notes **144** communicates with the patient data capture **140**, the clinical data capture **142** and the encounter data capture **146**.

Referring now to FIG. **5**, in a preferred embodiment, the point of care system **100** (FIG. **1**) includes a graphical user interface having a patient chart window **150** to capture patient information. The point of care system **100** presents a patient record graphically using a tabbed layout to organize patient data. The patient chart window **150** includes tabs for patient data **151**, clinical data **152**, encounter data **153** and progress notes **154**. Pointing and clicking on a tab on the patient chart window **150** opens a folder window **155** where a healthcare provider can enter and review patient data within the folder. For example, to activate progress notes **144** (FIG. **4**), the healthcare provider selects the progress notes tab **154** to display a list of progress note data in the folder window **155**. In a similar manner, to activate the patient data capture **140**, the clinical data capture **142** or the encounter data capture **146**, one selects the patient data tab **151**, the clinical data tab **142**, or the encounter data tab **153**, respectively.

To enter patient data, the healthcare provider clicks on the scroll down button **156** to select a form from a list of available forms to enter patient data. This activates the new forms box **157**. The provider then points and clicks on the new form button **158**. For example, FIG. **6** shows a new form window **161** displaying the pediatric problem form **162** selected by the healthcare provider using the scroll down button **156** (FIG. **5**). The healthcare provider fills out the pediatric problem form **162** using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "6/7/96 Stomach Ache" **164** and an electronic pen to enter initials **166** for identification. When done with patient data entry, the pro-

vider exits the form using the File Menu **168** and the point of care system **100** returns the provider to the patient chart window **150** (FIG. **5**). Referring back to FIG. **5**, the new form appears as the top entry of the list in the folder window **155**.

Similarly, to annotate patient data, the healthcare provider first selects an item to annotate by pointing and clicking on the item in a list displayed in the folder window **155**. The provider then clicks on the annotate button **159** to open the item in an annotate window **170**, as shown in FIG. **7**. For example, the annotate window **170** of FIG. **7** displays a blood test result **172**. As before, the healthcare provider annotates the blood test result document **172** using an input device, such as a keyboard, a mouse or an electronic pen. For example, the provider uses a keyboard to enter text "Out of Range" **174** and an electronic pen to circle **176** the out of range result. When done with annotations, the provider exits the form using the File Menu **178** and the point of care system **100** returns the provider to the patient chart window **150** (FIG. **5**). Note that the point of care system **100** tracks the review of patient data and identifies reviewed files with a mark **160** in the folder window **155**. By annotating patient data, a healthcare provider, such as a physician, can acknowledge reviewing patient data, provide instructions, such as directions for additional tests and procedures or prescriptions for medication to administer to the patient, and approve recommendations for treatment by other healthcare providers. Lastly, as shown in FIG. **8**, a healthcare provider uses the patient chart window **180** to view patient data. First, the healthcare provider selects a view item **182** by either pointing and clicking twice on the item in a list displayed in the folder window **184** or by pointing at the item in the list and pressing the view button **183**. The double click opens a viewer window **185** to display the view item **182**. For example, the viewer window **185** of FIG. **8** displays an x-ray **186**. As before, the healthcare provider may annotate the x-ray **186** with comments and observations by clicking on the annotate button **187**. The healthcare provider may likewise close the viewer window **185** by clicking on the close button **189**.

Certain additional structures in the point of care system **100** (FIG. **1**) will now be discussed with reference to FIGS. **9**, **10** and **11**. Referring now to FIG. **9**, an optional medication data capture **148** supplements the structure of the point of care system **100** of FIG. **4**. A medication data capture **148** allows a healthcare provider to monitor a patient's medications. The medication data capture **148** communicates with the patient data capture **140** to account for medications the patient is currently taking. The medication data capture **148** similarly communicates with the progress notes **144**, where a practitioner can monitor changes in a patient's condition resulting from medication therapies. Referring now to FIG. **10**, an optional practice guideline **149** supplements the structure of the point of care system of FIG. **4**. The practice guideline **149** provides references for practitioners to consult regarding courses of action to obtain a diagnosis and alternative treatments for various conditions. The practice guideline **149** communicates with the patient data capture **140**, the clinical data capture **142** and the encounter data capture **146** to assist the practitioner in selecting the appropriate course of action. The practice guideline **149** likewise communicates with the progress notes **144** to provide a healthcare provider with a historical context of the patient's condition and alternative treatments already attempted.

FIG. **11** shows a point of care system **100** having a medication data capture **148** and a practice guideline **149**. As before, the medication data capture **148** communicates with the patient data capture **140** and with the progress note **144**. Similarly, the practice guideline **149** communicates with patient data capture **140**, the clinical data capture **142**, the encounter data capture **146** and the progress note **144**. However, the practice guideline **149** may now communicate with the medication data capture **148** to address situations where accepted practice guidelines require a healthcare provider to prescribe and administer medications. In a preferred embodiment, the point of care system **100** includes the graphical user interface illustrated in FIG. **5**. Referring back to FIG. **5**, the patient chart window **150** includes tabs for medication data **191** and practice guidelines **193** that activate the medication data capture **148** and the practice guideline **149**, respectively. Similarly, pressing the medication manager button **192** activates the medication data capture **148** and the practice guideline **149**. A healthcare provider can enter, review and annotate patient medication data and practice guideline data as described previously.

Referring now to FIG. **12**, a block diagram illustrates the structure of the patient data repository **102**. The patient data repository **102** includes a patient locator **200**, a data manager **202** and a data interface **204**. The patient locator **200** generates a unique patient identifier (PID) **221** (FIG. **14**) for each patient and creates and maintains a table having PIDs for all patients who have data in the patient data repository **102**. All data records related to a patient **211**, **212**, **213**, **214**, **215**, **216**, **219** include and reference the patient's unique PID as shown in FIG. **13**.

With reference to FIG. **13**, upon creation of a patient record, the patient locator **200** creates a patient data structure **210** having the PID and the patient's name. In a preferred embodiment, the patient data structure **210** includes pointers to data structures having data within a patient record captured by the point of care system **100** and incorporated from external sources (e.g., a digital x-ray image file stored in a raster pixel format). Thus, the patient data structure **210** maintains a pointer to an interface files structure **211** having patient data transmitted from external sources. The patient data structure **210** likewise maintains pointers to a clinical data structure **212**, a progress note structure **213** and an encounter data structure **214**. These data structures include patient data captured by the clinical data capture **142**, progress notes **144** and encounter data capture **146**, respectively (FIG. **4**). In another preferred embodiment, the patient data structure **210** may include pointers to data structures having data generated by the reference database **104** and transferred by the legacy data system **106**. Thus, the patient data structure **210** may maintain pointers to a medication data structure **215** and a guideline data structure **216**. As described above, the medication **215** and guideline **216** data structures include patient data captured by the medication data capture **148** and the practice guideline **149**, respectively. In this embodiment, a reference data structure **217** may maintain pointers to the encounter data structure **214** and to the medication data structure **215** for access to reference information contained in a reference database **104**. Lastly, the patient data structure **210** may maintain a pointer to a legacy files structure **219** having patient data transmitted from the legacy data system **106**, such as an image of a patient chart.

FIG. **14** shows a logical view of a patient record **220** corresponding to the structure illustrated in FIG. **13**. The patient record **220** includes the PID generated by the patient locator **200** (FIG. **12**) in the patient data repository **102** (FIG. **1**). In addition, the patient record **220** includes patient data in a variety of data types generated by healthcare providers. Thus, the patient record includes text data **223**, such as

electronic mail and word processing documents from other healthcare providers, image data **225**, such as scanned physical documents, x-rays and CATSCANs, and audio data **227**, such as a physician's dictation and voice mail. Lastly, the patient record **220** has data tables **229**, such as a physician's ICD9 diagnosis codes and CPT procedure codes. In view of the structure of a patient record **220**, referring back to FIG. **12**, the data manager **202** uses the PID to store and retrieve patient records. Moreover, the data interface **204** permits communication with external sources to obtain patient data, such as demographic data, laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the patient data repository **102** to external healthcare providers.

With reference to FIG. **12**, the patient data repository **102** may optionally include a cache **206** for temporary storage of patient data and a data archive **208** for long term storage of patient data. In this embodiment, the data manager **202** coordinates the transfer of patient data to and from a data archive **208** into a cache **206**. For example, the data manager **202** may identify patient records that a healthcare provider needs for appointments scheduled at a future time and then transfer these patient records from the data archive **208** into the cache **206** for quick access prior to the scheduled appointment. Similarly, the data manager **202** may purge from the cache **206** records of patients who have not had recent appointments and whose records are already archived. The data manager **202** likewise tracks the location and description of patient data within the data archive **208** by associating the file name of the patient data within a patient record **220** with the patient identifier **221**. When possible, the data manager **202** will group data associated with a patient within the data archive **208** for rapid retrieval in a manner similar to files within a directory in an operating system. Thus, the data manager **202** assigns a directory to each patient identifier and then stores patient data within this directory.

FIG. **15***a* illustrates the process flow for the patient data repository **102** (FIG. **1**). For example, the point of care system **100** (FIG. **1**) issues a request for patient data **250**. With reference to FIGS. **15***a* and **12**, the patient locator **200** receives the request from the point of care system **100** and, at **251** attempts to find the PID for the record having the requested patient data. As determined at **252**, if no PID is found, the patient locator **200** reports an error **253**. At this point, the patient data repository **102** (FIG. **1**) may recover from the error **253** by either restarting the process or by ending the process. Otherwise, the patient locator **200** communicates the PID to the data manager **202**. The data manager **202** locates the patient record using the PID at **254**. As determined at **255**, in a system without cache **206** and without a data archive **208**, the data manager **202** delivers the requested data **256** to the point of care system **100**. In a system having a cache **206** and a data archive **208**, the data manager **202** determines at **257** if the requested data exists in the cache **206**. If so, the data manager **202** delivers the requested data **256** to the requester from the cache **206**. Otherwise, the data manager **202** first moves the data **258** from the data archive **208** to the cache **206** and then delivers the requested data **254** to the requester from the cache **206**.

In addition, FIG. **15***b*, in conjunction with FIG. **12**, illustrates the process for transferring data from a cache **206** to a data archive **208**. The data manager **202** monitors the contents of the cache **206**. To improve the performance of the cache **206**, the data manager **202** requests transfer **260** of data to the data archive **208** under certain conditions. For example, the data manager **202** may purge the cache **206** when data requested for storage in the cache would exceed its memory capacity. In this circumstance, the data manager **202** first transfers to the data archive **208** signed files and then data files in chronological order, i.e., oldest files first. Similarly, a healthcare provider can specify a predetermined time, such as 3 calendar days, or other selected conditions for transfer to the data archive **208**. As determined at **262**, if the cache **206** does not have the data to transfer, the process ends as the data manager **202** ignores the request. As determined at **264**, if the data in the cache **206** is not ready for transfer, the process ends and the data manager **202** queues the request for the next transfer of data to the data archive **208**. Data in the cache **206** is ready for transfer when a physician has reviewed and accepted it and when it has not been previously committed to the data archive **208**. Otherwise, the data manager **202** transfers data from the cache **206** to the data archive **208** at **266**.

Referring now to FIG. **16**, the data interface **204** of the patient data repository **102** includes an interface manager **270**, a data handler **272** and a communication interface **274**. To transfer and receive patient data from external sources (not shown), the interface manager **270** communicates with a data handler **272** and a communication interface **274**. In addition, the communication interface **274** communicates with the data handler **272** for conversion of received external patient data into formats recognized by the EMR system. The interface manager **270** creates and maintains an interface registry of data formats for external sources. Prior to data transfer or receipt by the EMR system, the interface manager **270** registers an interface for an external source. Upon registration of an interface, the interface manager **270** can provide the appropriate conversion routines for the data handler **272** to use for transfer of data to and receipt of data from an external source. These conversions are well understood by the relevant technologist.

FIGS. **17***a* and **17***b* illustrate the operation of the data interface **204** of the patient data repository **102** (FIG. **12**). Referring now to FIG. **17***a*, the data manager **202** issues a request **280** for patient data from an external source. At **282**, the interface manager **270** determines if the registry includes an interface for the external source, such as a laboratory or pharmacy. As determined at **282**, if the registry includes an interface for the external source, the communication interface **274** connects to the external source **284** to receive patient data. The data handler **272** retrieves the appropriate conversion routine for the external source to convert data **286**. In a preferred embodiment, the data handler **272** converts data from an external source into a database table for the appropriate PID. Lastly, the data manager **202** incorporates converted data **288** into the patient record. Otherwise, the interface manager **270** reports an error **289**. The data manager **202** may recover from the error **289** in several ways. First, the data manager **202** may invoke a module to register an interface for the external source so as to allow the process to continue. Second, the data manager **202** may end the process at this point. Lastly, the data manager **202** may restart the process in the event the external source was specified incorrectly.

Referring now to FIG. **17***b*, an external source requests data **290** from a patient record. As described above, the interface manager **270** determines at **292** if the registry includes an interface for the external source. As determined at **292**, if the registry includes an interface for the external source, the data manager **202** locates the requested data at **294** and the data handler **272** converts requested data at **296** to the format required by the external source. The communication interface **274** then sends the converted data to the

external source at **298**. For example, the patient data repository **102** may transmit a physician's prescription for medication to a hospital or pharmacy. If the registry includes no interface for the external source, the interface manager **270** reports an error **299**. Similarly, as discussed above for the process flow of FIG. **17***a*, the interface manager **270** may recover from the error **299** by restarting the process, ending the process or invoking a module to register the external source to allow the process to continue.

Referring now to FIG. **18**, a block diagram illustrates the structure of the optional reference database **104** (FIG. **1**). The reference database **104** includes a diagnosis module **300**, a medication manager **302** and a procedure module **304**. A healthcare provider can use the reference database **104** for assistance in diagnosing a patient's disease, prescribing medications and ordering supplemental procedures to treat the disease. The diagnosis module **300** communicates with a medication manager **302** to obtain information on medications indicated by a diagnosis. The medication manager **302** provides information on medications, such as proper dosages, allergies, contraindications, adverse interactions with other medications, and side effects. The diagnosis module **300** likewise communicates with a procedure module **304** to obtain information on the proper administration of procedures indicated by a diagnosis. The procedure module **304** provides information on procedures for treatment as indicated by the diagnosis. In many instances, the medication manager **302** communicates with the procedure module **304** regarding the administration of various medications.

In a preferred embodiment, the point of care system **100** provides access to the reference database **104** through a graphical user interface having a patient chart window **310** shown in FIG. **19**. A healthcare provider accesses the diagnosis module **300** and the procedure module **304** by pointing and clicking on a reference access button **312**.

As shown in FIG. **20**, the reference access button **312** produces a reference window **330** including the graphical interfaces for the diagnosis module **300** and the procedure module **304**. For example, to enter a diagnosis, a physician clicks on the scroll down button **331** adjacent to the system box **332** to produce a list of body systems. The physician selects the appropriate system and the diagnosis module **300** enters the selected system in the system box **332** and provides a list having specific diagnosis codes for the selected body system in the diagnosis box **334**. The physician then selects the appropriate diagnosis code and clicks on the add button **336** adjacent to the diagnosis selection box **337**. The diagnosis module **300** enters the selected diagnosis code to the diagnosis selection box **337**. The physician may repeat the above steps to add multiple diagnosis codes to the diagnosis selection box **337**. In a similar manner, a physician uses the scroll down button **331** adjacent to the topic box **333** to select the appropriate procedure topic. The procedure module **304** enters the selected procedure topic in the topic box **333** and provides a list of procedure codes in the procedure box **335**. The physician now selects the appropriate procedure code and adds it to the procedure selection box **338** by clicking on the add button **336** adjacent to the procedure selection box **338**. The physician may likewise repeat the above steps to add multiple procedure codes to the procedure selection box **338**. The physician completes entry of diagnoses and procedures by clicking on the done button **339** to return to the patient chart window **310** of FIG. **19**.

The healthcare provider similarly accesses the medication manager **302** (FIG. **18**) by clicking on a medication button **192** (FIG. **19**). Referring now to FIG. **21**, the medication button **314** activates a medication manager window **350**. The physician can review the patient's history by viewing the medication history box **351** and the diagnosis history box **352** before prescribing any new medications. The physician can also review any patient allergies in the allergy box **353**. The physician can select a medication by entering the name of the medication in the name box **354**. Note that as the physician enters the root letters of a medication name, a list of medications with the root letters appears in the medication list box **355**. As before, the physician selects a medication from the list by clicking on it and the medication manager **302** places the selected medication in a selection box **356**. If there are no contraindications or allergies for the patient, the physician prescribes the medications listed in the selection box **356** by clicking on the prescribe button **357**.

Otherwise, if a contraindication exists, a warning appears in a warning bar **358** to alert the physician. In view of the warning, the physician can investigate the effects of the medication by clicking on the results button **359**. Referring now to FIG. **22**, the results button produces a medication interaction window **361**. A medication selection box **362** displays the medications selected and under consideration by the physician. An allergy list box **363** displays the patient's allergens. Folder tabs **364** include labels describing the medication combinations and interactions. The physician clicks on one of these folder tabs **364** to display the contents of the folder in the viewing box **365**. The physician can then evaluate the information on the interaction including potential adverse patient reactions. The physician clicks on the done button **366** to return to the medication manager window **350** of FIG. **21**. The physician can make any needed revisions to the medications selected in the manner described above. Afterwards, the physician exits the medication manager **302** by clicking on the exit button **360**.

Referring now to FIG. **23**, a block diagram illustrates the structure of the optional legacy data system **106** as shown in FIG. **1**. The legacy data system **106** includes a data source **370** and a converter **372**. The data source **370** comprises physical data **374**, such as paper based records and photographs, and electronic mainframe data **376**. The converter **372** receives information from the data source **370** and transforms the information into an electronic format compatible with the EMR system. For example, to input physical data **374**, such as paper or image based data, into a patient record, the converter **372** comprises a scanner to digitize the physical data into a binary file format for incorporation into the patient's record. To input electronic mainframe data **376**, the converter **372** employs the same mechanism used for transfer or receipt of patient data from external sources. As described before, the converter **372** determines if an interface exists for the mainframe data, selects the appropriate data handler and converts the data into the proper format for incorporation into a patient record.

II. EMR System Configurations

FIG. **24** illustrates one possible configuration for the EMR system of the present invention. The system comprises a wide area network (WAN) **402**, the World Wide Web (Web) **404** portion of the Internet, and remote web servers **406**, **408**, **410** communicating with web browsers **412**. The WAN **402** comprises a plurality of local area network (LAN) servers supporting local and remotely located healthcare providers. For example, the WAN **402** includes LANs supporting Scripps Health **414** and Sharp Memorial **430** in San Diego and Cedars Sinai **432** and Loma Linda **434** in Los Angeles, Calif. In one presently preferred embodiment, the server comprises a multi-processor personal computer hav-

ing Intel Pentium processors, such as a Compaq Proliant 4500R 5/100 Model 2, communicating with a fault tolerant, error correcting storage device, such as a Hewlett Packard 20XT Optical Jukebox having 20 gigabytes of storage capacity. The LAN **400** includes a backup server **426** and several peripherals, such as a scanner **424** to input documents and a laser printer **422** to print out documents. In a preferred embodiment, the LAN backbone comprises an Ethernet twisted pair cable configured in a general star topology. Similarly, the scanner **424** comprises a Fujitsu M3093EX scanner using Kofax KIPP ImageControls software and the laser printer **422** comprises a Hewlett Packard LaserJet 4Plus. Healthcare providers may access the LAN **400** using a desktop computer **416**, a laptop computer **418** or wireless pen computer **420**. In a preferred embodiment, the desktop computer **416** comprises a Compaq Deskpro 5/75 Model 630, the laptop computer **418** comprises a IBM ThinkPad 760CD and the pen computer **420** comprises a Fujitsu Stylist 1000 configured with a Solectek AirLAN PCMCIA network adapter for wireless LAN access. The EMR system also provides for communication through the World Wide Web. For example, remote healthcare providers may access the WAN **402** on the Web using the domain name "www.westest.com" **436**. Thus, a healthcare provider located in Boston, Mass. may access a patient record resident on the Scripps Health server **414**, located in San Diego, Calif., using a web browser **412**, such as Microsoft Explorer or Netscape Navigator, communicating with a Web server in Boston, Mass. having the domain name "www.boston.com" **406**.

In a preferred embodiment, servers **414**, **426**, desktop **416**, or laptop **418** computers and peripherals, such as printers **422** or scanners **424**, communicate with each other and with the Web using a network operating system, such as Microsoft Windows NT, Windows 95 or Windows for Workgroups. Similarly, pen computers **420** use the Microsoft Windows for Pen Computing operating system. In another preferred embodiment, the servers, computers and peripherals communicate using an operating system supporting Web browsers on computer networks, such as Unix, Novell Netware or Apple System 7.0. In yet another preferred embodiment, the EMR system includes servers, computers and peripherals networked using mixed network operating systems, such as Unix, Netware and Windows. For example, the LAN **400** may operate on a Windows NT network operating system, whereas the LAN **430** may operate on an Apple System 7.0 network, and the Web server "www.boston.com" **406** may operate on a Unix operating system. Thus, the EMR system supports communication among a variety of hardware components, such as printers **422**, scanners **424** and pen computers **420**, using a variety of network operating systems, such as Windows, Netware or Unix. In a preferred embodiment, healthcare providers, such as clinics and laboratories, may also communicate with the EMR system using modem links and standard v.34 modem devices, such as a US Robotics Sportster 28,800 modem.

The EMR system includes several databases of electronic information, such as the medication manager **302** and the data manager **202**. In a preferred embodiment, the EMR system implements a relational database language that conforms to American National Standards Institute (ANSI) standard SQL-92, a 580 page specification for the SQL relational database language. A database language standard specifies the semantics of various components of database management systems (DBMS). In particular, it defines the structures and operations of a data model implemented by the DBMS, as well as other components that support data definition, data access, security, programming language interface and data administration. The SQL-92 standard specifies data definition, data manipulation, and other associated facilities of a DBMS that supports the relational data model. SQL is old in the art and additional information on SQL-92 is available in ANSI specification X3.135-1992, hereby incorporated by reference.

Similarly, in another preferred embodiment, relational databases in the EMR system support the Open Database Connectivity (ODBC) model. ODBC is an application program interface (API) that allows client applications running under Microsoft Windows to access data from a variety of data sources, including relational and non-relational DBMS. These data sources may reside on a client machine or they may be located on a remote server communicating through a network common to the client machine. Under ODBC, data sources may vary in complexity from shrink-wrap databases, such as Microsoft Access, running under Windows on a client machine to more sophisticated, proprietary relational DBMS running on a Unix server or mainframe computer. For a client application to access data from a data source, a dynamic link library (DLL) driver must exist for each data source to be accessed. For additional information on ODBC is available from Inside ODBC, by Karl Geiger, hereby incorporated by reference.

II. SUMMARY

The electronic medical record system of the present invention advantageously overcomes several limitations of existing technologies and alternatives. Because it is more efficient and cost effective to move data, instead of physical records and healthcare providers, the present invention eliminates the need to create and maintain any physical data records. In contrast to other systems, the present invention creates and maintains all patient data electronically. Thus, there is no need to find, pull, move, update, file and replace physical charts. As a result, healthcare providers no longer require substantial shelving and storage space for physical files. The present invention likewise eliminates the mishandling, loss and destruction of patient data typically associated with maintenance of physical data records.

Using the present invention, healthcare providers enter patient data immediately at the point of care. Thus, the EMR system captures each piece of data at its source at the time of entry, including time and healthcare provider identification. The EMR system thus provides a complete audit trail for all patient data. The audit trail, in turn, permits inexpensive analysis of outcomes, utilization and compliance. For example, outcomes typically refer to the effectiveness of a treatment plan. Thus, the EMR system enables a healthcare provider to analyze patient recovery times and incurred costs to measure the efficacy of the treatment plan. Similarly, utilization typically refers to how well available resources are utilizing time. Thus, the EMR system provides the capability to analyze utilization of physicians, nurses, staff and equipment as well as time utilization for patients, such. as wait times for referrals, lab results and physician examinations. Lastly, compliance typically refers to conformance with government and accreditation standards and regulations. The EMR system provides tools to enable healthcare providers to measure conformance to standards and regulations. To facilitate entry of patient data at the point of care, the invention provides touch screens for entry of lab orders, medications, diagnoses and procedures. The invention likewise provides instant access to a patient's electronic medical record by authorized healthcare providers from any geographical location. Thus, the EMR system enables autho-

rized healthcare providers to access and update patient files using wireless pen-based personal computers. In addition, authorized healthcare providers can access a record while other healthcare providers use the same record. By providing simultaneous access to patient data, the present invention enables real-time collaboration among multiple healthcare providers.

The availability of electronic data permits instant, sophisticated analysis of a patient's clinical data. Thus, the EMR system can create graphs of a patient's vital signs and lab results or the system can provide an analyze patient information to identify medication interactions and allergies. Using the present invention, a healthcare provider can likewise select, sort, and analyze patient data to identify relationships among the data considered. In addition, the EMR system provides flexibility in the creation and maintenance of patient data repositories. Thus, the present invention can support a large healthcare enterprise distributed across a large geography as well as a single physician office. Moreover, the present invention ensures patient confidentiality through the use of a tiered password system. The EMR system provides several levels of security for access to patient data. For example, a system administrator may have global password access to any patient data for system maintenance and debug purposes, whereas physicians may have access only to patient records within their specialty and nurses and staff may have access to only those patient records within their immediate care. In addition, a patient may request restricted access to their data by only certain personnel. Thus, in contrast to physical records, the EMR system provides superior protection of patient data.

In addition, the present invention is useful in legal, manufacturing and general administration environments. For example, the present invention is capable of organizing, maintaining and protecting legal files in an attorney's office. Thus, the EMR system can store and retrieve scanned images of paper documents, such as deeds and assignments, as well as other native file formats, such as word processing files. The EMR system organizes and retrieves this data in a manner akin to that of a patient's medical record. Upon entry of a client data into the EMR system, attorneys can annotate documents, transfer information to and from other systems, or create new data for automatic filing in the client or case file. Similarly, the EMR system is useful for management of procurement or regulatory data in a manufacturing context. Thus, the EMR system can organize and maintain material safety data sheets (MSDS) as well as other data pertinent to materials procurement, such as conformance to specification measurements and inspection data for received lots, in a manufacturing environment. Lastly, the EMR system is useful for general administrative files in any organization. For example, the present invention is applicable to employee files in human resources, customer files in sales and approved suppliers in procurement. The EMR system can organize and retrieve data within these files in the manner as patient data in a patient data record. As discussed above, upon entry of a data into the EMR system, users can annotate documents, transfer information to and from other systems, or create new data for automatic filing in the respective file.

Those skilled in the art may practice the principles of the present invention in other specific forms without departing from its spirit or essential characteristics. Accordingly, the disclosed embodiments of the invention are merely illustrative and do not serve to limit the scope of the invention set forth in the following claims.

What is claimed is:

1. A medical records system, comprising:

a point of care system to capture patient data at a point of care wherein the point of care system comprises:

patient data capture to enter information provided by a patient,

a clinical data capture, in data communication with the patient data capture to enter clinical data for the patient,

an encounter data capture, in data communication with the patient data capture, to enter diagnoses and procedures administered to the patient, and

progress notes, in data communication with the patient data capture, the clinical data capture and the encounter data capture, to enter information related to changes in the patient's condition, and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

2. The medical records system of claim 1, further comprising a medication data capture, in data communication with the patient data capture and the progress notes, to enter medication information for the patient.

3. The medical records system of claim 1, further comprising a practice guideline for reference to accepted medical practices, wherein the practice guideline communicates with the patient data capture, the clinical data capture, the progress notes and the encounter data capture.

4. The medical records system of claim 3, further comprising a medication data capture, in data communication with the patient data capture, the progress notes and the practice guideline, to enter medication information for the patient.

5. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that accepts SQL data queries.

6. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises a server computer having access to patient data stored in a relational database that is ODBC compatible.

7. A medical records system, comprising:

a point of care system to capture patient data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system, wherein the patient data repository comprises:

a patient locator having a patient identifier,

a data manager, in communication with the patient locator, to organize patient data for storage and retrieval using the patient identifier, and

a data interface, in communication with the data manager, to transmit patient data to external systems and to receive patient data from the external systems.

8. The medical records system of claim 7, wherein the patient data repository further comprises:

a cache, in communication with the data manager, to temporarily store the patient data for retrieval; and

a data archive, in communication with the cache, to permanently store the patient data.

9. The medical records system of claim 8, wherein the cache is located on a server computer.

10. The medical records system of claim 8, wherein the cache is distributed across a computer network.

11. The medical records system of claim 8, wherein the data archive comprises a jukebox having at least one storage device.

12. The medical records system of claim 11, wherein the at least one storage device is a recordable optical disk.

13. The medical records system of claim 11, wherein the at least one storage device is a magnetic disk drive.

14. The medical records system of claim 7, wherein the data interface comprises:

a communication interface to send and receive patient data from external systems;

an interface manager, in communication with the communication interface, to set the communication interface for either transmission or receipt of the patient data from the external systems; and

a data handler, in communication with the interface manager and with the communication interface, to convert selected patient data into a selected data format.

15. A medical records system, comprising:

a point of care system to capture patient data at a point of care;

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and

a reference database in communication with the point of care system.

16. The medical records system of claim 15, wherein the reference database comprises:

a diagnosis module having diagnosis codes indicative of a condition of a patient;

a procedure module, in communication with the diagnosis module, having procedure codes indicative of a treatment to administer to the patient; and

a medication manager, in communication with the diagnosis module and with the procedure module, having information on medication to administer to the patient.

17. A medical records system, comprising:

a point of care system to capture patient data at a point of care;

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system; and

a legacy data system in communication with the patient data repository.

18. The medical records system of claim 17, wherein the legacy data system comprises:

a data source having patient data; and

a converter, in communication with the data source, to convert the patient data into a selected format for transfer to the patient data repository.

19. The medical records system of claim 18, wherein the data source comprises physical data.

20. The medical records system of claim 18, wherein the data source 20 comprises a mainframe computer having electronically stored patient data.

21. The medical records system of claim 18, wherein the converter comprises a scanner.

22. A medical records system, comprising:

a point of care system to capture patient data at a point of care wherein the point of care system provides for annotation of the patient data; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the patient data for access by the point of care system.

23. The medical records system of claim 22, wherein the annotation acknowledges review of the patient data.

24. The medical records system of claim 22, wherein the annotation includes instructions for patient care.

25. The medical records system of claim 22, wherein the annotation indicates approval.

26. A medical records system, comprising:

a point of care system to capture data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises interface files and wherein the patient record includes,

a patient identifier, and

at least one data structure including the patient identifier and the data.

27. A medical records system, comprising:

a point of care system to capture data at a point of care; and

a patient data repository, in communication with the point of care system and with external systems, to store and organize the data in a patient record for access by the point of care system, wherein the data comprises legacy files and wherein the patient record includes,

a patient identifier, and

at least one data structure including the patient identifier and the data.

28. A method of using an electronic medical records system, comprising the steps of:

capturing patient data electronically at the point of care;

organizing the patient data so as to form a patient record;

filing the patient record; and

retrieving the patient record to access the patient data for use in the care of a patient.

29. The method of claim 28, wherein the step of retrieving the patient record includes annotating the patient data.

30. The method of claim 28, further comprising the step of evaluating the patient data so as to make a diagnosis.

31. The method of claim 30, wherein the step of evaluating the patient data comprises consulting a diagnosis module to review diagnosis information.

32. The method of claim 30, further comprising the step of prescribing a medication.

33. The method of claim 32, wherein the step of prescribing a medication comprises consulting a medication manager to review medication information.

34. The method of claim 30, further comprising the step of administering a treatment.

35. The method of claim 34, wherein the step of administering a treatment comprises consulting a procedure module to review procedures to administer the treatment.

36. A method of retrieving patient data in an electronic medical records system having a patient data repository, comprising the steps of:

obtaining a patient identifier;

locating a patient record corresponding to the patient identifier in the patient data repository;

determining the location of the patient data within the patient record.

37. The method of claim 36, further comprising the step of delivering the patient data.

38. The method of claim 36, wherein the patient data repository includes a cache and a data archive.

39. The method of claim 38, further comprising the step of delivering the patient data when the patient data is located in the cache.

40. The method of claim 38, further comprising the steps of:

moving the patient data from the data archive when the patient data is not located in the cache; and

delivering the patient data.

41. A method of managing a patient data repository having a cache and a data archive, comprising the steps of:

monitoring a status of data within the cache; and

moving the data to the data archive when the status exceeds a threshold.

42. The method of claim 41, wherein the threshold comprises a selected time and the status comprises the duration of time the data has been in the cache.

43. The method of claim 41, wherein the threshold comprises a selected portion of the storage capacity of the cache and the status comprises the filled portion of the cache.

44. A method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of:

finding an interface for the external source;

connecting to the external source using the interface; and

converting patient data for transfer between the external source and the electronic medical records system.

45. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the electronic medical records system to the external source.

46. The method of claim 44, wherein the step of converting patient data for transfer comprises converting patient data for transfer from the external source to the electronic medical records system.

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[54] METHOD AND SYSTEM FOR MAINTAINING AND UPDATING COMPUTERIZED MEDICAL RECORDS

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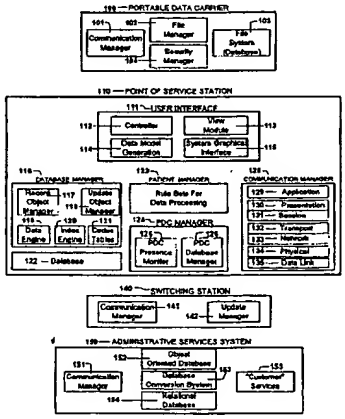
Ciciani et al. "Analysis of Concurrency–Coherency Control Protocols for Distributed Transaction Processing Systems with Regional Locality ", IEEE Transacitons on Software Engineering, v18, n10, pp. 899–914, Oct. 1992.

Primary Examiner—Wayne Amsbury
Assistant Examiner—Charles L. Rones
Attorney, Agent, or Firm—Harness, Dickey & Pierce, P.L.C.

[57] ABSTRACT

A distributed database architecture stores medical information in a self-updating system that employs point-of-service stations disposed at convenient medical service locations. Each patient carries a portable data carrier such as a smart card that contains the patient's complete medical history. Interaction between the portable data carriers and the point-of-service stations effects a virtual communication link that ties the distributed databases together without the need for online or live data connections. The point-of-service stations are also interconnected over a communications network through a switching station that likewise does not rely on online, live communication. The database system uses an object-oriented update object to distribute data that has been generated when a portable data carrier is not physically present and to automatically distribute data without the necessity of accessing a masterfile.

76 Claims, 12 Drawing Sheets



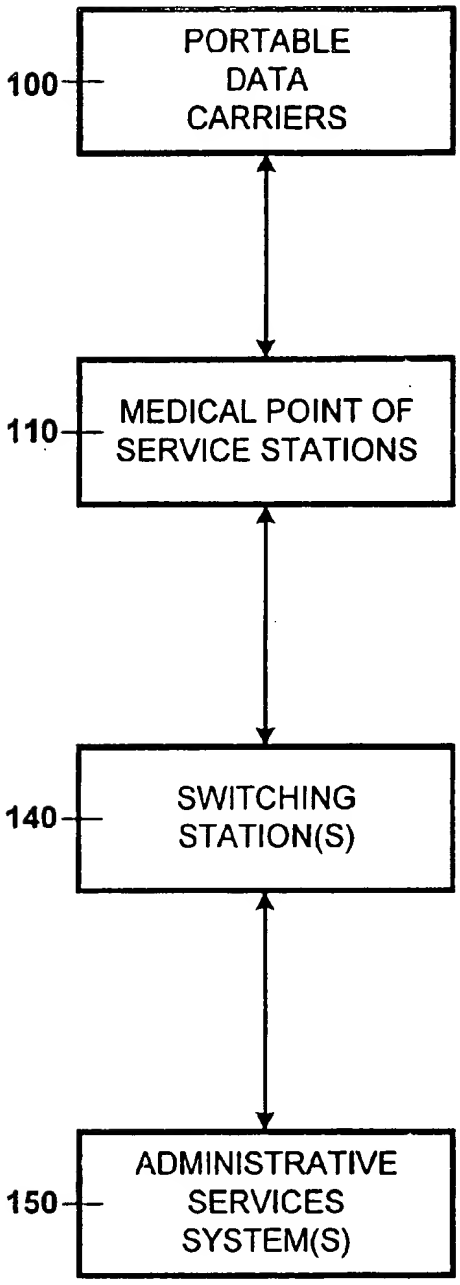

100
PORTABLE DATA CARRIERS
110
MEDICAL POINT OF SERVICE STATIONS
140
SWITCHING STATION(S)
150
ADMINISTRATIVE SERVICES SYSTEM(S)

FIG. 1

200 — FIELD OBJECT

Field Type Identifier	Field Length	Field Value

210 — COLLECTION OF FIELD OBJECTS

Field Type Identifier	Field Length	Field Value

FIG. 2

220 — RECORD OBJECT

Record Type Identifier	Unique Record Object Identifier	Collection Of Field Objects

230 — COLLECTION OF RECORD OBJECTS

Record Type Identifier	Unique Record Object Identifier	Collection Of Field Objects		
		Field Type	Field Length	Field Value

FIG. 3

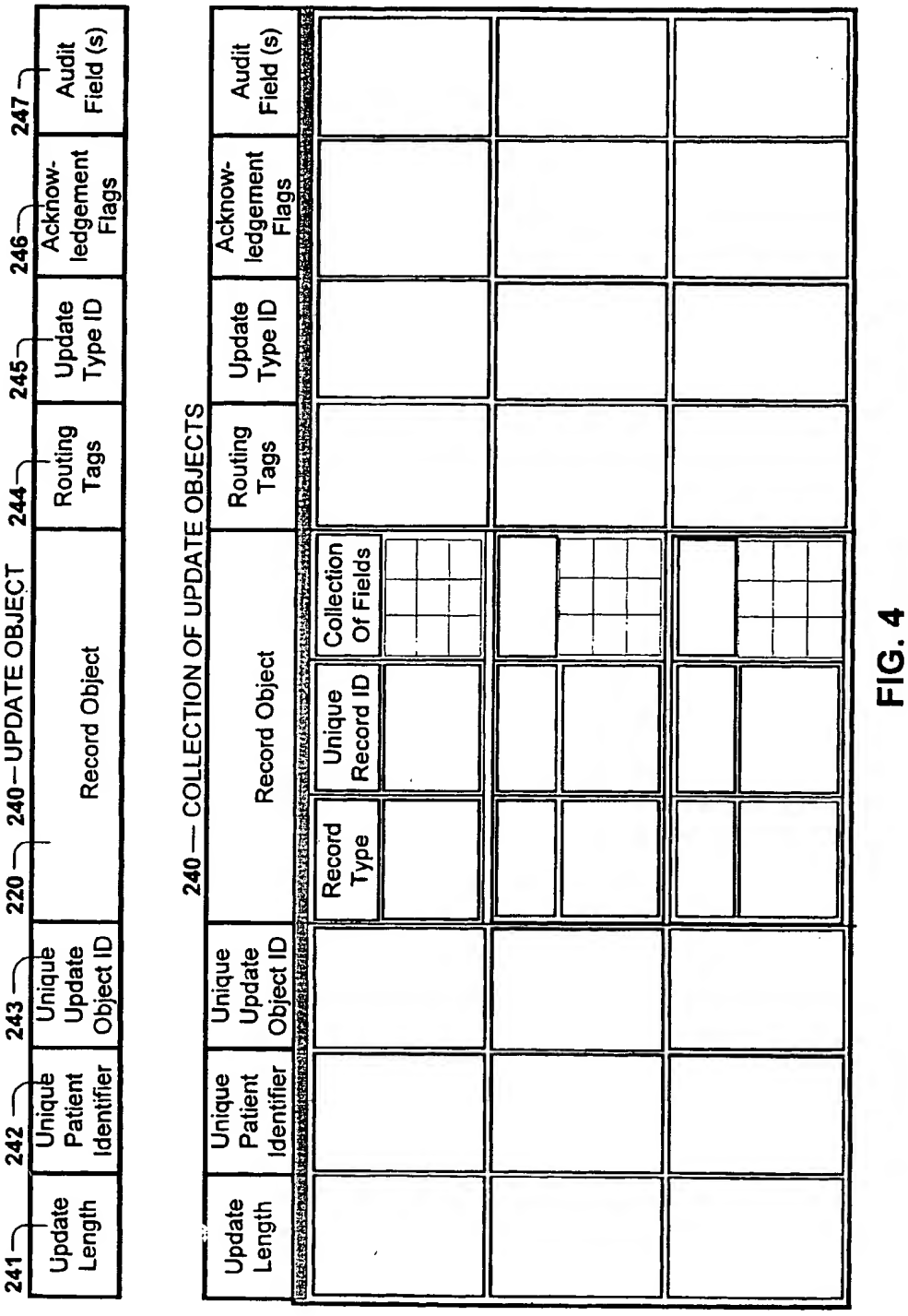

241
Update Length
242
Unique Patient Identifier
243
Unique Update Object ID
220
240—UPDATE OBJECT
Record Object
244
Routing Tags
245
Update Type ID
246
Acknow-ledgement Flags
247
Audit Field (s)
240— COLLECTION OF UPDATE OBJECTS
Update Length
Unique Patient Identifier
Unique Update Object ID
Record Object
Record Type
Unique Record ID
Collection Of Fields
Routing Tags
Update Type ID
Acknow-ledgement Flags
Audit Field (s)

FIG. 4

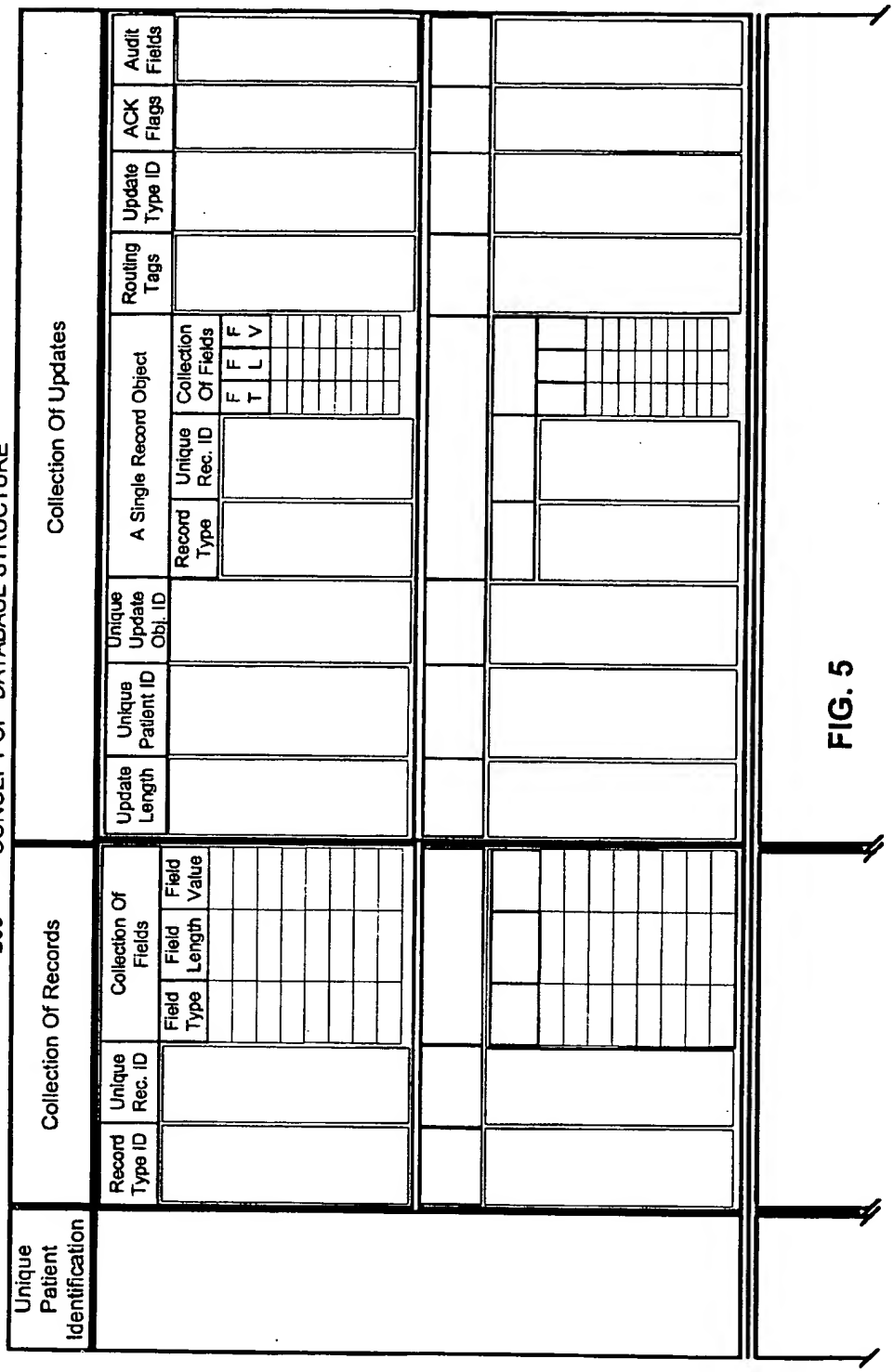

260 — CONCEPT OF DATABASE STRUCTURE
Unique Patient Identification
Collection Of Records
Record Type ID
Unique Rec. ID
Collection Of Fields
Field Type
Field Length
Field Value
Collection Of Updates
Update Length
Unique Patient ID
Unique Update Obj. ID
A Single Record Object
Record Type
Unique Rec. ID
Collection Of Fields
F T
F L
F V
Routing Tags
Update Type ID
ACK Flags
Audit Fields

FIG. 5

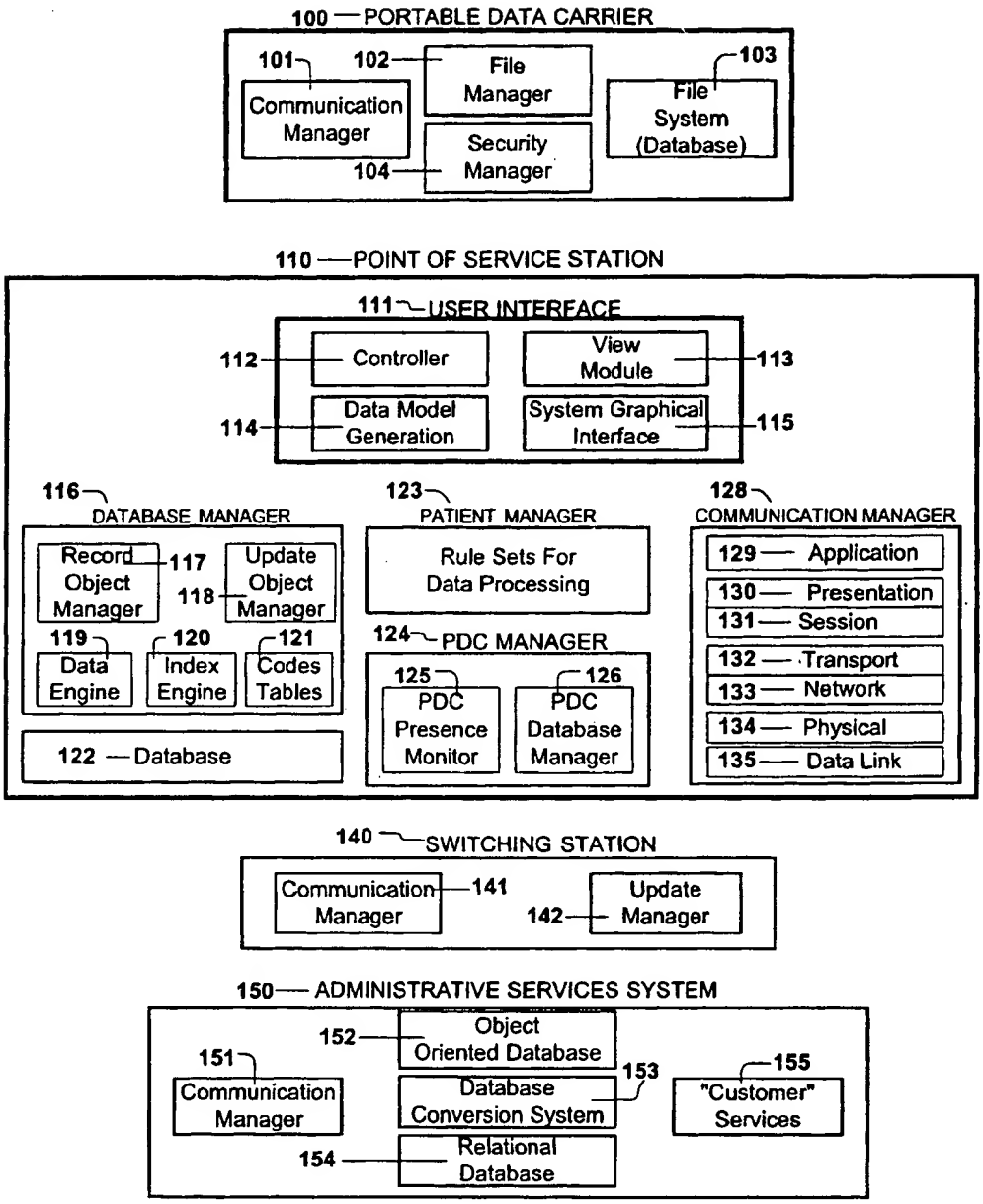

100 PORTABLE DATA CARRIER
101
Communication Manager
102
File Manager
103
File System (Database)
104
Security Manager
110 POINT OF SERVICE STATION
111 USER INTERFACE
112
Controller
View Module
113
114
Data Model Generation
System Graphical Interface
115
116
DATABASE MANAGER
Record Object Manager
117
Update Object Manager
118
119
Data Engine
120
Index Engine
121
Codes Tables
122 Database
123
PATIENT MANAGER
Rule Sets For Data Processing
124 PDC MANAGER
125
PDC Presence Monitor
126
PDC Database Manager
128
COMMUNICATION MANAGER
129 Application
130 Presentation
131 Session
132 Transport
133 Network
134 Physical
135 Data Link
140 SWITCHING STATION
Communication Manager
141
142
Update Manager
150 ADMINISTRATIVE SERVICES SYSTEM
151
Communication Manager
152
Object Oriented Database
153
Database Conversion System
154
Relational Database
155
"Customer" Services

FIG. 6

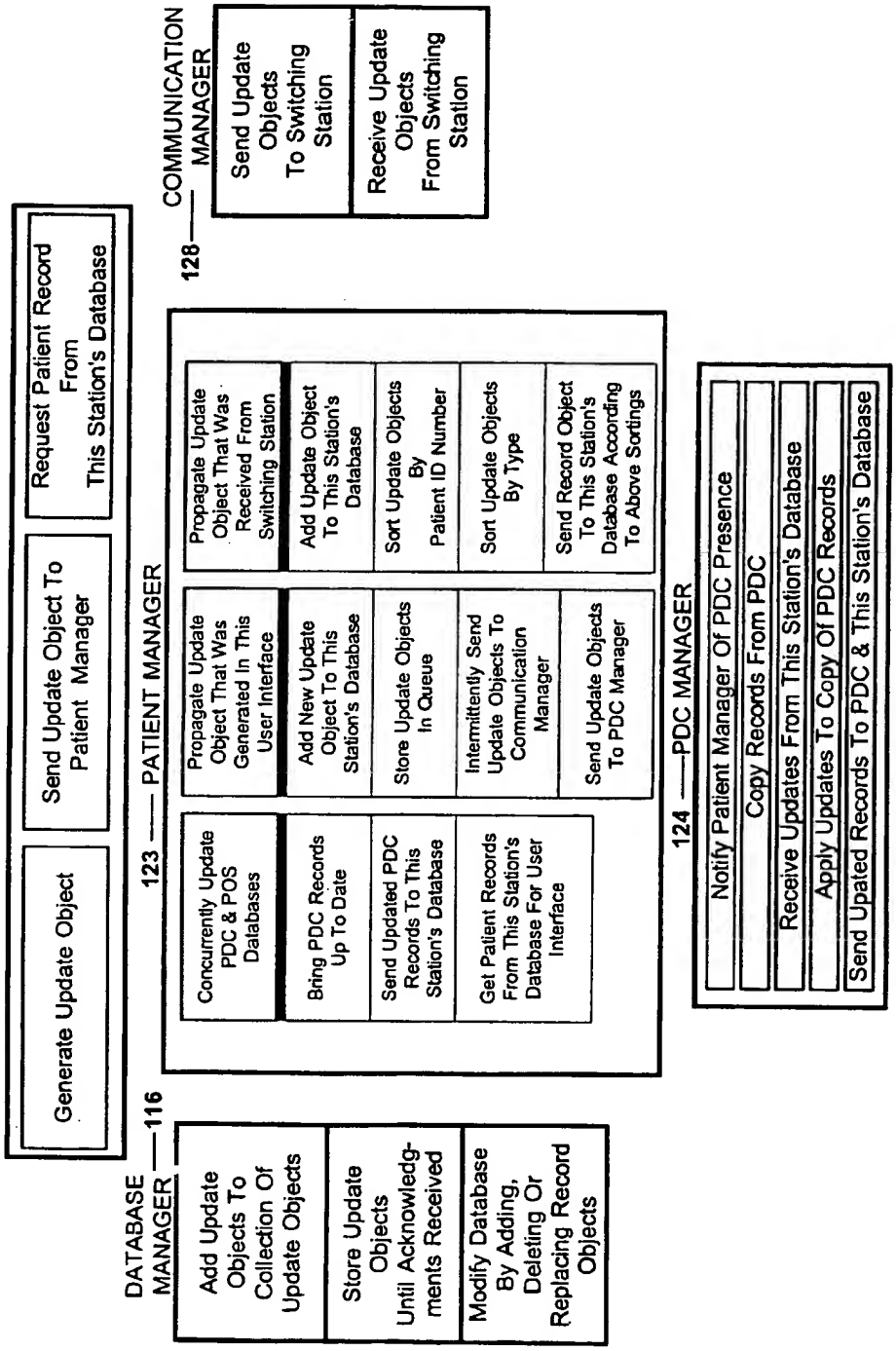

111 USER INTERFACE
Generate Update Object
Send Update Object To Patient Manager
Request Patient Record From This Station's Database
DATABASE MANAGER 116
Add Update Objects To Collection Of Update Objects
Store Update Objects Until Acknowledg-ments Received
Modify Database By Adding, Deleting Or Replacing Record Objects
123 PATIENT MANAGER
Concurrently Update PDC & POS Databases
Bring PDC Records Up To Date
Send Updated PDC Records To This Station's Database
Get Patient Records From This Station's Database For User Interface
Propagate Update Object That Was Generated In This User Interface
Add New Update Object To This Station's Database
Store Update Objects In Queue
Intermittently Send Update Objects To Communication Manager
Send Update Objects To PDC Manager
Propagate Update Object That Was Received From Switching Station
Add Update Object To This Station's Database
Sort Update Objects By Patient ID Number
Sort Update Objects By Type
Send Record Object To This Station's Database According To Above Sortings
124 PDC MANAGER
Notify Patient Manager Of PDC Presence
Copy Records From PDC
Receive Updates From This Station's Database
Apply Updates To Copy Of PDC Records
Send Upated Records To PDC & This Station's Database
128 COMMUNICATION MANAGER
Send Update Objects To Switching Station
Receive Update Objects From Switching Station

FIG. 7

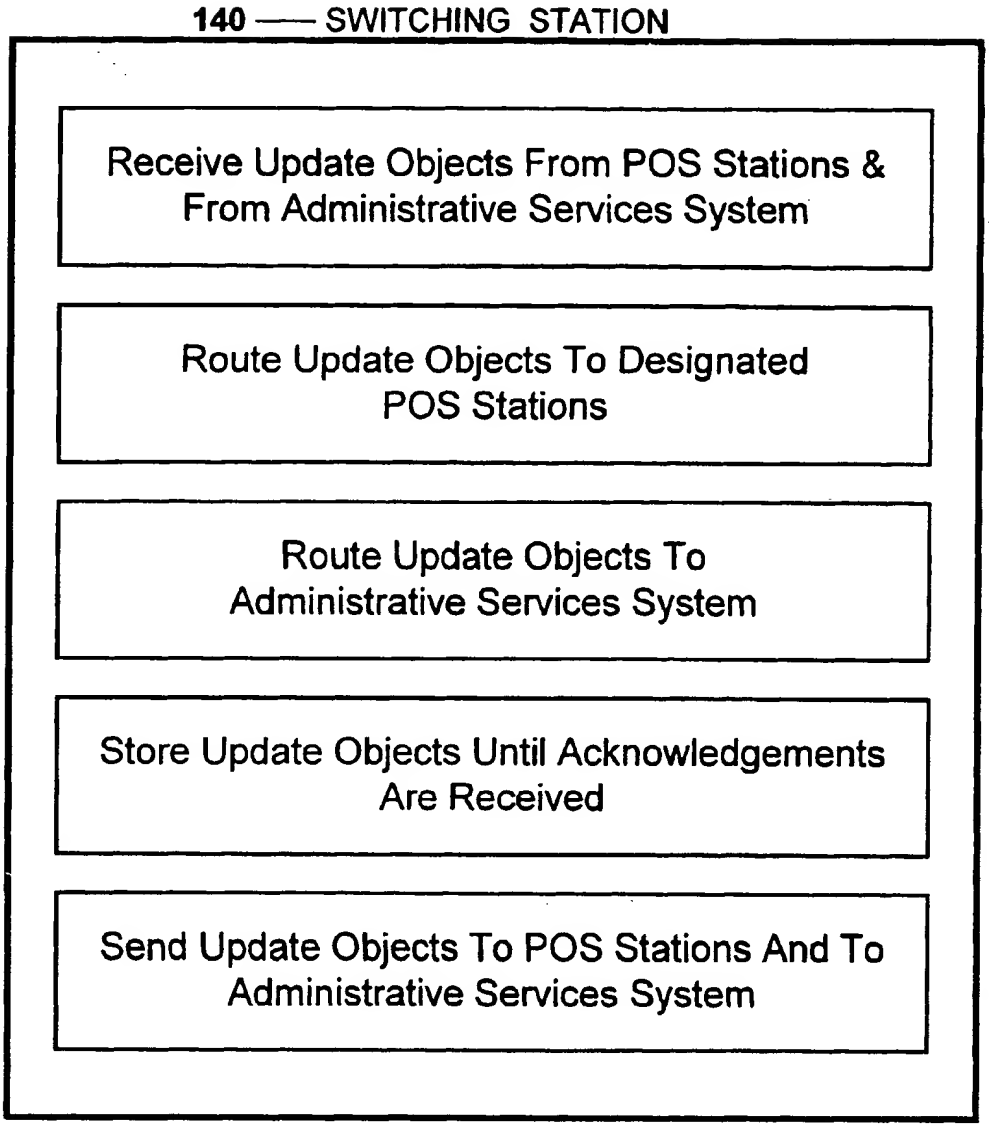

140 —— SWITCHING STATION
Receive Update Objects From POS Stations & From Administrative Services System
Route Update Objects To Designated POS Stations
Route Update Objects To Administrative Services System
Store Update Objects Until Acknowledgements Are Received
Send Update Objects To POS Stations And To Administrative Services System

FIG. 8

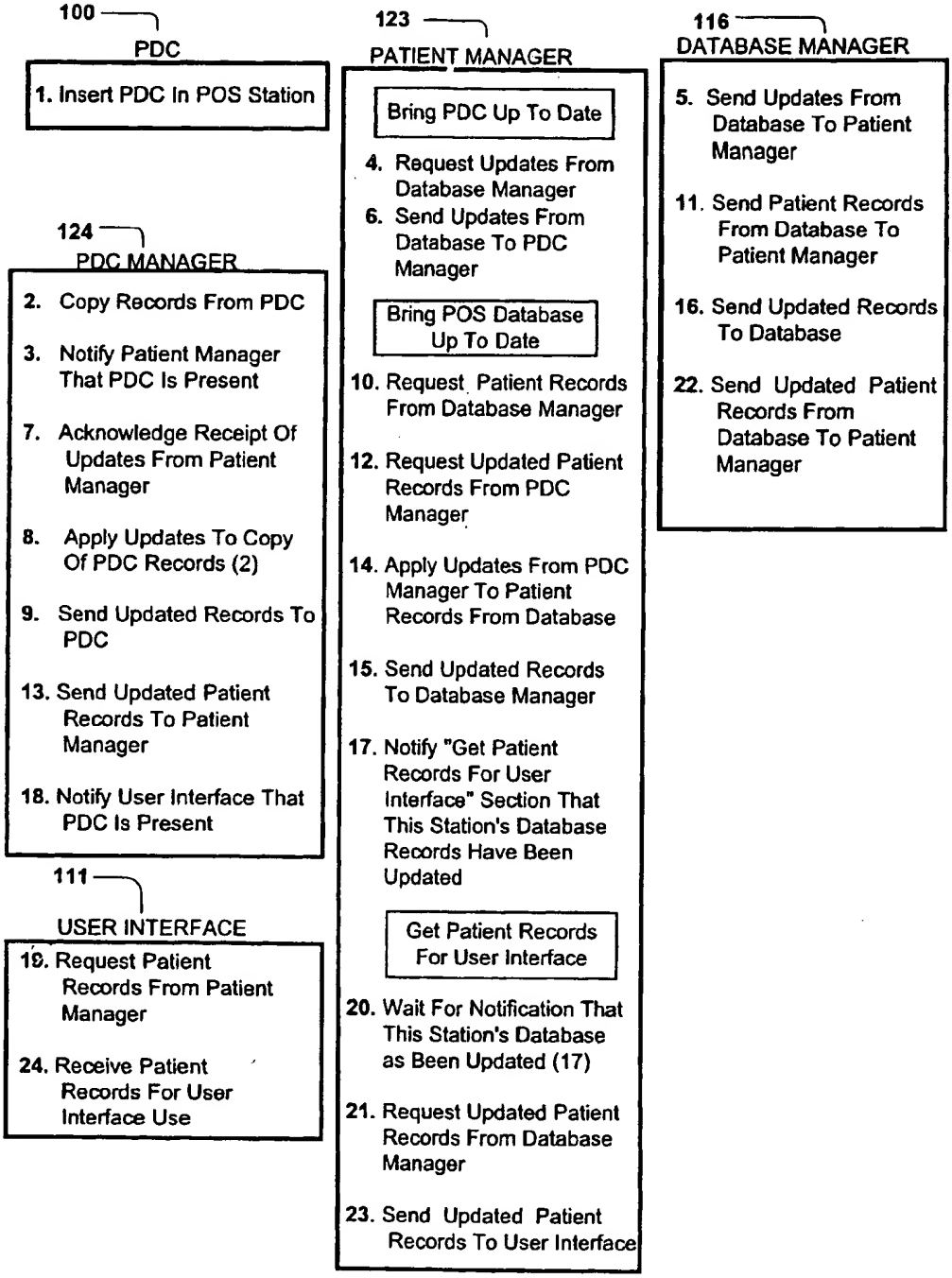

100
PDC
1. Insert PDC In POS Station
124
PDC MANAGER
2. Copy Records From PDC
3. Notify Patient Manager That PDC Is Present
7. Acknowledge Receipt Of Updates From Patient Manager
8. Apply Updates To Copy Of PDC Records (2)
9. Send Updated Records To PDC
13. Send Updated Patient Records To Patient Manager
18. Notify User Interface That PDC Is Present
111
USER INTERFACE
19. Request Patient Records From Patient Manager
24. Receive Patient Records For User Interface Use
123
PATIENT MANAGER
Bring PDC Up To Date
4. Request Updates From Database Manager
6. Send Updates From Database To PDC Manager
Bring POS Database Up To Date
10. Request Patient Records From Database Manager
12. Request Updated Patient Records From PDC Manager
14. Apply Updates From PDC Manager To Patient Records From Database
15. Send Updated Records To Database Manager
17. Notify "Get Patient Records For User Interface" Section That This Station's Database Records Have Been Updated
Get Patient Records For User Interface
20. Wait For Notification That This Station's Database as Been Updated (17)
21. Request Updated Patient Records From Database Manager
23. Send Updated Patient Records To User Interface
116
DATABASE MANAGER
5. Send Updates From Database To Patient Manager
11. Send Patient Records From Database To Patient Manager
16. Send Updated Records To Database
22. Send Updated Patient Records From Database To Patient Manager

FIG. 9

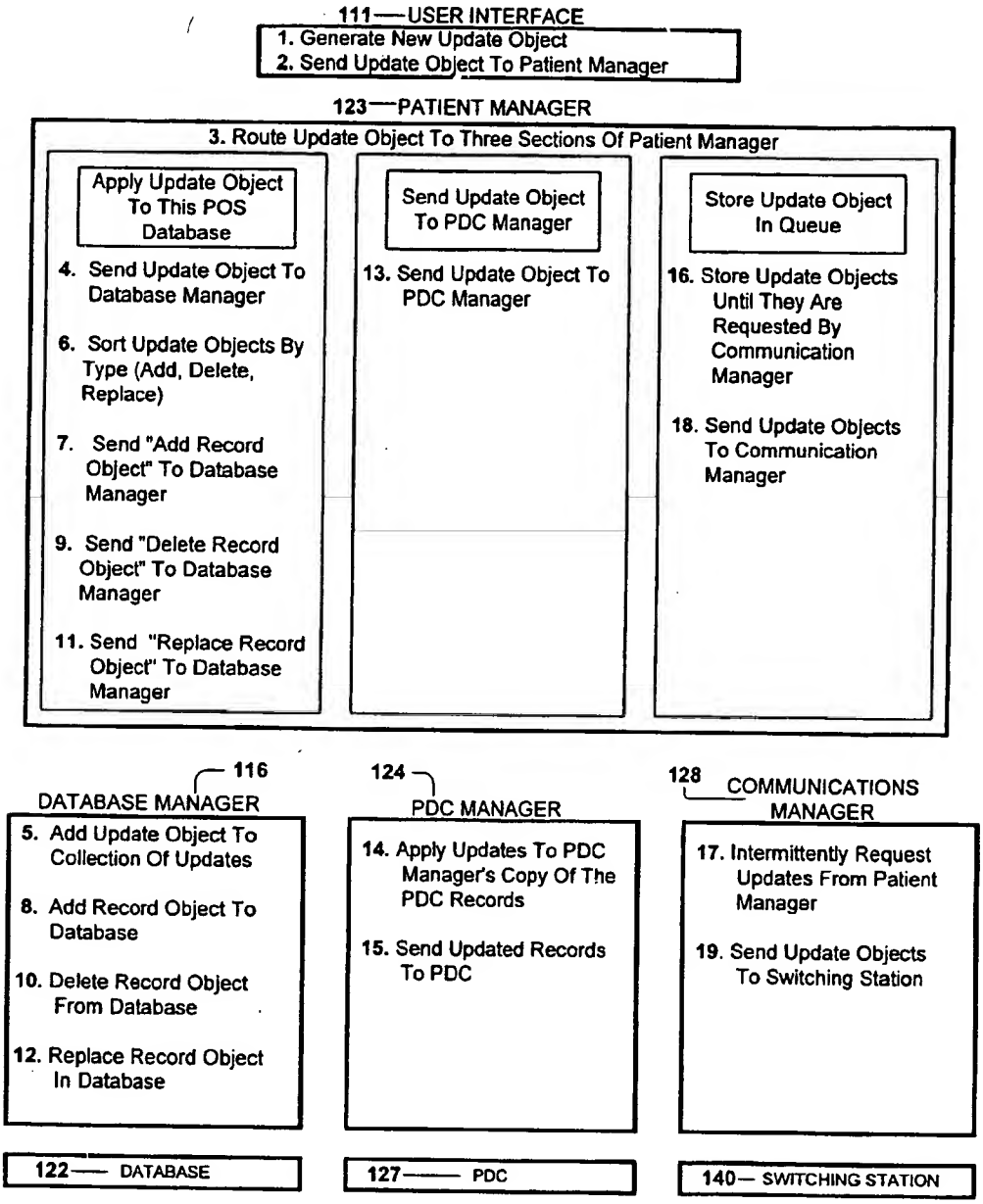

111—USER INTERFACE
1. Generate New Update Object
2. Send Update Object To Patient Manager
123—PATIENT MANAGER
3. Route Update Object To Three Sections Of Patient Manager
Apply Update Object To This POS Database
4. Send Update Object To Database Manager
6. Sort Update Objects By Type (Add, Delete, Replace)
7. Send "Add Record Object" To Database Manager
9. Send "Delete Record Object" To Database Manager
11. Send "Replace Record Object" To Database Manager
Send Update Object To PDC Manager
13. Send Update Object To PDC Manager
Store Update Object In Queue
16. Store Update Objects Until They Are Requested By Communication Manager
18. Send Update Objects To Communication Manager
116
DATABASE MANAGER
5. Add Update Object To Collection Of Updates
8. Add Record Object To Database
10. Delete Record Object From Database
12. Replace Record Object In Database
124
PDC MANAGER
14. Apply Updates To PDC Manager's Copy Of The PDC Records
15. Send Updated Records To PDC
128
COMMUNICATIONS MANAGER
17. Intermittently Request Updates From Patient Manager
19. Send Update Objects To Switching Station
122— DATABASE
127— PDC
140— SWITCHING STATION

FIG. 10

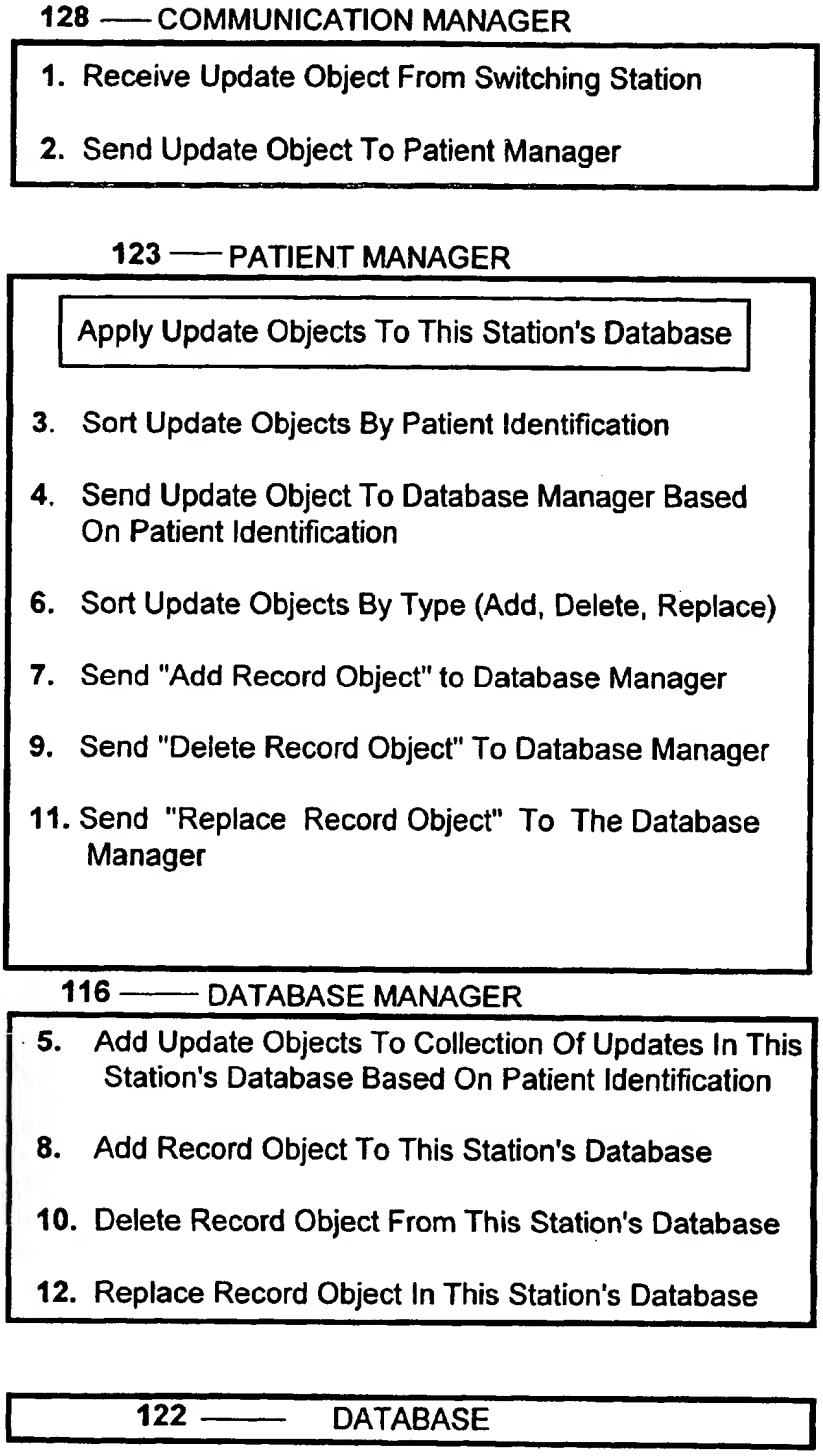

128 — COMMUNICATION MANAGER
1. Receive Update Object From Switching Station
2. Send Update Object To Patient Manager
123 — PATIENT MANAGER
Apply Update Objects To This Station's Database
3. Sort Update Objects By Patient Identification
4. Send Update Object To Database Manager Based On Patient Identification
6. Sort Update Objects By Type (Add, Delete, Replace)
7. Send "Add Record Object" to Database Manager
9. Send "Delete Record Object" To Database Manager
11. Send "Replace Record Object" To The Database Manager
116 — DATABASE MANAGER
5. Add Update Objects To Collection Of Updates In This Station's Database Based On Patient Identification
8. Add Record Object To This Station's Database
10. Delete Record Object From This Station's Database
12. Replace Record Object In This Station's Database
122 — DATABASE

FIG. 11

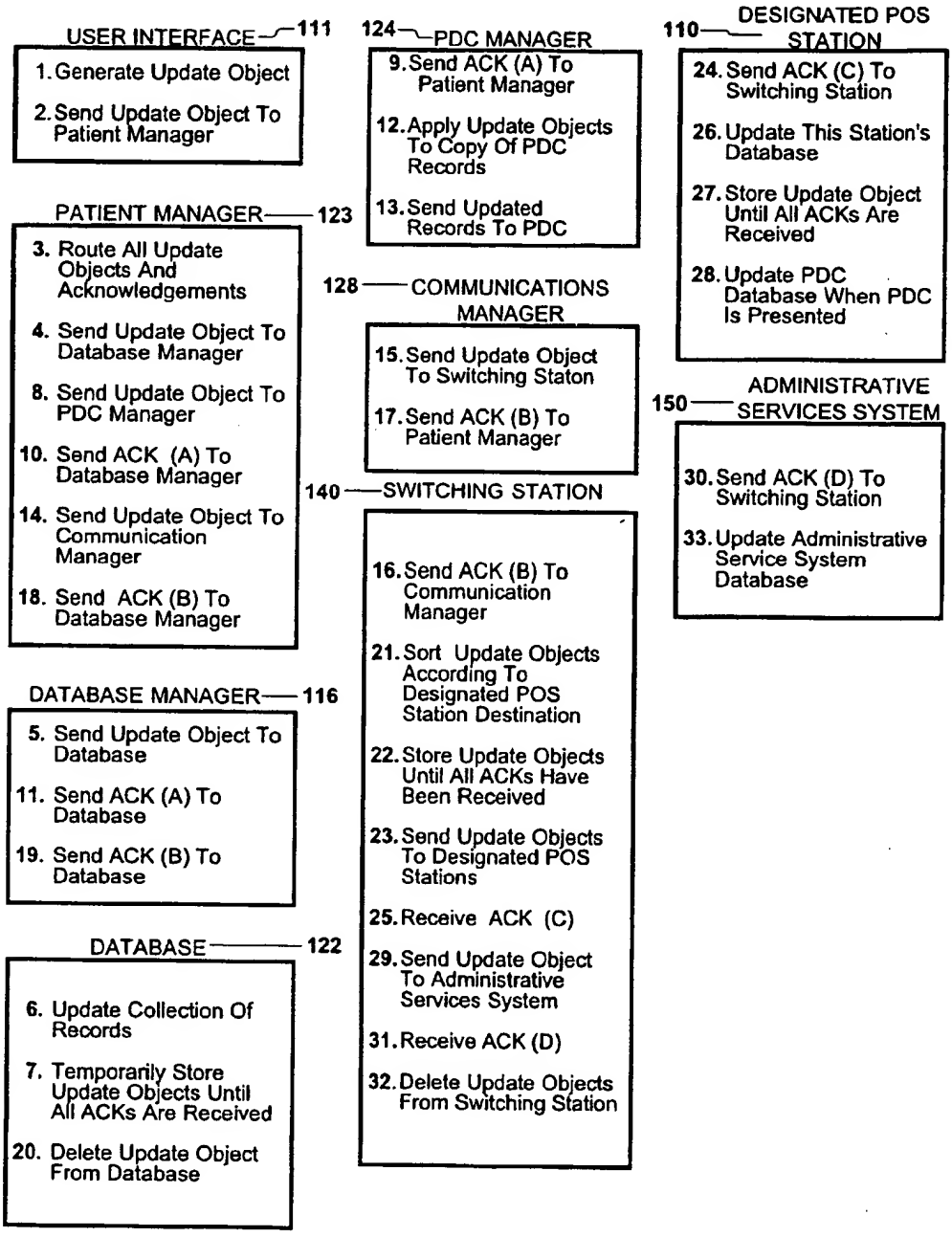

USER INTERFACE 111
1. Generate Update Object
2. Send Update Object To Patient Manager
PATIENT MANAGER 123
3. Route All Update Objects And Acknowledgements
4. Send Update Object To Database Manager
8. Send Update Object To PDC Manager
10. Send ACK (A) To Database Manager
14. Send Update Object To Communication Manager
18. Send ACK (B) To Database Manager
DATABASE MANAGER 116
5. Send Update Object To Database
11. Send ACK (A) To Database
19. Send ACK (B) To Database
DATABASE 122
6. Update Collection Of Records
7. Temporarily Store Update Objects Until All ACKs Are Received
20. Delete Update Object From Database
124 PDC MANAGER
9. Send ACK (A) To Patient Manager
12. Apply Update Objects To Copy Of PDC Records
13. Send Updated Records To PDC
128 COMMUNICATIONS MANAGER
15. Send Update Object To Switching Staton
17. Send ACK (B) To Patient Manager
140 SWITCHING STATION
16. Send ACK (B) To Communication Manager
21. Sort Update Objects According To Designated POS Station Destination
22. Store Update Objects Until All ACKs Have Been Received
23. Send Update Objects To Designated POS Stations
25. Receive ACK (C)
29. Send Update Object To Administrative Services System
31. Receive ACK (D)
32. Delete Update Objects From Switching Station
110 DESIGNATED POS STATION
24. Send ACK (C) To Switching Station
26. Update This Station's Database
27. Store Update Object Until All ACKs Are Received
28. Update PDC Database When PDC Is Presented
150 ADMINISTRATIVE SERVICES SYSTEM
30. Send ACK (D) To Switching Station
33. Update Administrative Service System Database

FIG 12

METHOD AND SYSTEM FOR MAINTAINING AND UPDATING COMPUTERIZED MEDICAL RECORDS

BACKGROUND AND SUMMARY OF THE INVENTION

A. Field of the Invention

The present invention relates generally to computerized medical information systems. More specifically, it relates to maintaining and updating computerized medical records.

The invention is based on a distributed database network architecture, in which a plurality of portable data carriers (PDCs) and point-of-service (POS) stations interact to maintain the currency of the medical records of a plurality of patients. Each PDC contains the medical record of an individual patient. Each POS station contains a system for generating and propagating medical data specific to that medical care site.

The PDCs and POS stations contain independent, but interrelated, databases; and a major function of the presently described invention is to keep the information in these databases current.

In addition to serving as one of the database repositories in this network, each PDC also serves as a communication link between the POS stations. Each patient carries their own medical record from one station to another on their own PDC.

Furthermore, the invention utilizes object-oriented tools and structures that include: (1) dynamic objects called "update objects" and (2) data processing "rule sets" which are stored throughout the above described network, working together, these update objects and rule sets establish, route, organize, store and update the medical information of a plurality of patients.

B. Description of Related Art

The healthcare industry has long recognized the need for a computerized medical information system that can maintain a comprehensive and current record of each patient's medical status over space and time.

Although keeping such information in computerized databases might seem simple, providing efficient and cost-effective access to those databases and keeping all data in the databases current, are daunting tasks due to some technical inefficiencies in traditional distributed database systems, and due to the size and mobility of patient populations.

Whereas, it has been possible to successfully implement traditional centralized on-line computer information systems for geographically limited populations, such as within hospitals, it has not been possible to simply scale-up these systems to accommodate larger, more disperse patient populations in the outpatient setting.

The complex, wide-spread interactions of medical outpatient care require a wide area network architecture. However, available distributed database networks exhibit significant shortcomings when they are applied to electronic data interchange applications that entail complex independent transactions at numerous disparate point-of-service locations.

The major problems that make traditional network models unsuitable for many point-of-service applications, such as outpatient medical care, are: (1) inefficient access to needed data, (2) difficulty in maintaining data currency throughout the system and (3) cost.

From the data access standpoint, traditional transaction-oriented networks define a master data file which must be coordinated and updated at one main site and then must be made available, in whole or in part, to peripheral dependent locations.

In order to have access to current data, these traditional systems must be continuously available on-line; and as the complexity of the transaction-based application increases, overload and bottleneck problems ensue; and the communication channels become more complicated and costly. Furthermore, the integrity of the whole network continuously and precariously depends on the reliability of these physical communication channels.

To date, accessing a central file, at some point, is the only networking solution that allows for the coordination of data updates that have been generated at geographically distinct locations. And unfortunately, all of these network systems experience overload, bottleneck, service interruption or coordination delay problems, because of their need to update and then redistribute, data from a masterfile.

Outpatient medical transactions are so diverse, as well as being so geographically and temporally complex, that the anticipated problems of data access, data currency and cost of the traditional centralized systems, become prohibitive. These are the primary reasons that, currently, there are no successful, broad-based computerized outpatient medical record systems.

SUMMARY OF THE INVENTION

The present invention takes a different approach. It does not depend on the presence of a central database, or a single masterfile. It is a new type of distributed database network system in which medical data items are automatically propagated from their sites of origin to several different memory storage sites, independently and selectively. The memory sites exist in: (1) portable data carriers (PDC), (2) medical point-of-service (POS) stations and (3) administrative services systems.

Although the presently described system is applicable to inpatient medical care, it is most advantageous in the outpatient setting.

In the presently preferred embodiment, the PDC is a microprocessor integrated circuit chip card, commonly known as a smart card. This card serves as a data storage device on which patients carry a copy of their own medical record.

Each card can carry a significant amount of medical data. In the present embodiment, this includes, but is not restricted to: diagnoses, surgeries, obstetrical data, status of therapeutic treatments, diagnostic test results, current and past medications, allergies, diet, durable medical equipment, blood type, advanced directives, immunizations, birth data, social history, family history, physician office visits, hospitalizations and emergency room visits. In addition, the card carries physician orders, such as medication prescriptions, laboratory or X-ray tests, referrals to consultant physicians, surgical procedures and the like. All of this data is directly transported between the POS stations of the system on the PDCs.

The POS stations are computer systems positioned at locations where patients receive medical care, such as physician offices, pharmacies, laboratories, radiology units, hospitals, diagnostic and treatment centers, emergency treatment sites and urgent care centers. Each of the POS stations may be custom-configured to that provider's specific medical application.

For example, a physician office POS station may, among other functions, generate new diagnoses and physician

orders; and may store and have access to the entire medical record of all the patients that are cared for at that particular site. Whereas, a pharmacy POS station, in addition to other functions, may read the medication prescription orders that are designated on the patient's PDC; and further, may indicate on the PDC that the medication has been dispensed. However, the pharmacy POS station may not have read or write access to any other portion of the patient's PDC record.

This independent PDC-POS database design allows "patient specific" and "site specific" medical data to be present when and where it is needed, at every medical POS location. Each patient carries their own medical record with them to each POS site, thus resolving the issue of timely and efficient access to data. Bottleneck, system overload and service interruption problems are avoided.

Besides serving as data memory sites, the PDCs also serve as one of the main communication links between POS stations. Stored within their PDC, patients actually carry their medical data from one POS station to another. We are describing this aspect of the invention as "off-line" communication, to distinguish it from "traditional on-line" communication. For transaction-based applications, "on-line" implies continuous availability of a physical telecommunication link and live or real-time data transfer. In contrast, by carrying their own data with them, the PDCs allow intermittent, focused, "off-line" coupling, which is much more efficient and much less expensive.

By way of brief illustration, when a patient visits their doctor, the patient's PDC is read by the doctor's POS station and this automatically transfers medical information between the PDC and the station, so that the more current data is propagated and stored in both places.

Thereafter, the doctor may diagnose an illness, and prescribe certain medications. This information is input and stored in the doctor's POS station and also transferred to the patient's PDC before they leave the office.

Later, when the patient visits the pharmacy to fill the prescription, the patient's PDC is read by the POS station at the pharmacy. This causes the current prescription information to be propagated to the pharmacy station. It may not be necessary for the pharmacy POS station to have access to all of the medical information on the PDC. Indeed, some of the information may be confidential or unnecessary to filling the prescription. The internally stored rule sets in the pharmacy POS station govern what information can be obtained from the PDC and what information is excluded.

The pharmacy then inputs its data related to filling the prescription, thus updating the PDC further. The pharmacy POS station also stores the data it generated in its own internal memory.

In the preceding illustration, only two stations were described. However, as indicated previously, the system contemplates a plurality of POS stations, each being custom-configured to that provider's medical application.

These POS stations are all in "virtual" communication with each other because the collective rule sets of the system are designed to propagate data from one station to another, using the PDCs as the communication medium rather than traditional telecommunication channels.

Furthermore, a second type of "virtual" communication system has been designed which does utilize traditional telecommunication channels; but describes an alternate method of propagating data over these channels. The data is transmitted via "update objects."

The core of each update object is an element of information or an item of data that has been generated by a medical transaction at a POS station. Examples of such data would be an X-ray report or a laboratory test result. In addition to this basic core of medical data, each update object also contains processing tags. These tags, along with corresponding data processing "rule sets" located throughout the system, guide each update object to its targeted PDC, POS and administrative databases, independently. Furthermore, the processing tags and rule sets also function to automatically assimilate the data element into the independent databases.

The update object is designed to distribute data that has been generated when a PDC is not physically present, such as a laboratory test result which becomes available after the patient has already left the laboratory. Also, it is designed to automatically distribute data without needing to access a masterfile.

For example, an update object may be created at a laboratory POS station. The update object contains a test result and is tagged with specific destination identifiers such as the POS address of the patient's primary physician.

The update object is then routed through a switching station which is essentially an electronic data exchange system containing rule sets designed to propagate the medical data over traditional communication channels from one network POS station to any other station. The system is not dependent on a specific method of data transmission.

This system does differ from traditional switching mechanisms, in that, rather than routing update information to a single masterfile, each data element is automatically routed to any of a number of distributed databases throughout the network. Furthermore, all data is routed selectively, meaning that it is only transported to locations at which it is needed. This system provides significant data processing efficiency. Also, communication between each POS station and the switching station only needs to occur intermittently, resulting in significant cost savings.

When the update object arrives at the physician's POS station, it is stored in the database and it is also transferred to the patient's PDC, the next time the patient arrives for medical care. In addition to direct PDC-POS communication linkages, this update object-switching station design provides a second automatic and selective mechanism for the POS stations and the PDCs to remain current without needing to access a masterfile.

In addition to the above advantages, each update object persists in critical locations throughout the network, until the data element it contains has successfully reached all designated databases. This feature provides significant data security and does not rely on the continuous integrity of the telecommunication linkages to assure that data is appropriately propagated.

As mentioned previously, this system also contains an administrative services system which provides the management services related to medical activities services such as data backup, billing, medical and financial auditing, and report generation.

One of the key concepts of this invention is the establishment of a network of truly independent databases, which are connected by "virtual" communication systems and are automatically modified and kept current, without accessing a masterfile. This concept is made functional by combining PDCs, which are both independent databases and "off-line" communication channels, with independent POS stations and administrative services systems, all utilizing flexible and unique computer tools and rules.

This invention provides a practical, efficient, and cost-effective solution to the problems associated with complex,

high-volume, transaction-oriented networking applications, such as outpatient medical information systems.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a system overview block diagram of the presently preferred system for maintaining and updating computerized medical records;

FIG. 2 is a block diagram illustrating the presently preferred field object data structure;

FIG. 3 is a block diagram illustrating the presently preferred record object data structure;

FIG. 4 is a block diagram illustrating the presently preferred update object data structure;

FIG. 5 is a table diagram illustrating the overall database structure employed by the presently preferred implementation;

FIG. 6 is a block diagram illustrating the principal subsystems employed in the portable data carrier, the point-of-service station, the switching station and the administrative services system;

FIG. 7 is a block diagram describing the rules set of the presently preferred implementation, illustrating the presently preferred locations at which the rules are implemented;

FIG. 8 is a block diagram of the switching station architecture;

FIG. 9 is a block diagram illustrating the rules set used by the presently preferred embodiment to handle communications and updates between the portable data carrier and point-of-service station databases;

FIG. 10 is a block diagram illustrating the process by which an update object generated by a point-of-service station is propagated;

FIG. 11 is a block diagram illustrating the process by which an update object received from a switching station is propagated;

FIG. 12 is a block diagram illustrating the processing rules employed by the preferred embodiment in routing an update object through the entire system.

DESCRIPTION OF THE PREFERRED EMBODIMENT

II System Overview

FIG. 1 illustrates the basic components of the presently preferred medical information system. The system includes a plurality of portable data carriers (PDCs) **100**, and medical point-of-service (POS) stations **110**, one or more switching stations **140** and one or more administrative services systems **150**.

A Portable Data Carrier **100**

The presently preferred PDC is an integrated electronic circuit chip card containing a microprocessor and memory and it is commonly known as a "smart card." It has data processing and memory capabilities. It may contain an independent, on-board power source and a digital display. It serves as a data storage medium and a communication device.

The smart card is presently preferred, because it is relatively economical and may easily be carried in the purse or wallet. It has sufficient memory capacity to store a patient's entire medical record; it has processing capabilities to handle changes in the medical record; it can accommodate administrative functions such as demographic changes and financial transactions; and it has numerous inherent security features to accommodate medical privacy and confidentiality concerns.

By integrating software and hardware design, each PDC is structured to communicate with a plurality of medical POS stations. In the presently preferred embodiment, the PDC communicates with the POS stations through electric contacts, although contactless interface is also possible.

As depicted in FIG. 6, the presently utilized PDC conceptually has four principle subsystems: a communication manager **101**, a file manager **102**, a security manager **104** and a file system (database) **103**. These will be described later.

B Point-of-Service Station **110**

A medical POS station contains the computer system located at any site where medical services can be provided. These sites include, but are not restricted to, physician offices, diagnostic and therapeutic treatment centers, laboratories, radiology departments, emergency and urgent care treatment sites, pharmacies, hospitals and durable medical equipment suppliers.

In the presently preferred embodiment, the hardware and software at each site are specific for the particular type of medical service provided there. A POS station may be implemented using a variety of different personal computers loaded with the system's specific operating programs described herein. Various peripheral devices such as touchscreens, scanners and devices with digital interfaces such as laboratory test equipment may also be utilized.

The presently preferred embodiment uses a true multitasking operating system, IBM's OS/2. This allows a POS operator to interact with the system with no perceived delay while the PDC is concurrently being interrogated and updated. It also allows several different application programs to run simultaneously. This could be advantageous in medical offices that want to use their POS stations for functions such as word processing, or out-of-system billing or record keeping.

The present system utilizes an object-oriented language, C++ and object-oriented program and system designs.

Referring to FIG. 6, presently, the major POS station subsystems are: user interface **111**, database manager **116**, database **122**, patient manager **123**, PDC manager **124** and communication manager **128**. These will be described in more detail later.

C Switching Station **140**

The presently preferred embodiment uses asynchronous modems to connect each POS station to a switching station. Communications over these modems are encrypted to help protect the security of the system and to preserve the confidentiality of individual patient's medical information.

The present design utilizes intermittent communication of batched data. The data that is generated at each POS station is temporarily stored on site and then transmitted to a switching station, using an "end-of-day" or an "as-needed" routine. This is more efficient, less expensive and more reliable than continuous on-line communication.

Each switching station may be configured with various combinations of PCs, minicomputers, or mainframes. In the presently preferred embodiment, the switching station is a network of PCs. Each PC contains: a communication manager module **141** and an "update manager" module **142** (FIG. 6). Together, these two units organize and direct the routing of data between various POS stations and also between each POS station and the administrative services system.

D Administrative Services System **150**

An administrative services system deals with the management issues related to medical care. The types of services provided are optional and can include functions such as data

backup, billing, auditing, data analysis and reporting. Each system can be constructed using various hardware and software combinations to provide particular "customer services." "Customer" refers to anyone who utilizes or benefits from the services of the system, such as patients, care providers, healthcare managers, healthcare payers and researchers.

Each administrative services system may be configured utilizing various combinations of PC's, minicomputers or mainframes. The presently preferred embodiment builds the system around a microcomputer or minicomputer which contains: a communication manager **151**, an object-oriented database **152**, a database conversion system **153**, a relational database **154** and an array of "customer services" **155**. See FIG. **6**.

Over secure channels, the communication manager coordinates bi-directional communication with the switching station. It also provides "external" connections with the information systems of customers such as healthcare managers, payers and researchers.

The object-oriented database maintains a copy of the medical record of all patients using this system. It maintains records in the same format as the PDC and POS databases; and can be used as a backup resource if there is a breakdown in the PDC-POS-switching station portion of the system.

This preferred embodiment further contains a database conversion system which converts the object-oriented database to a relational database. Incorporating a common-format, standardized database structure and language into the present invention, facilitates functions such as report generation and communication with external commercial systems such as those commonly used by healthcare managers, payers and researchers.

The relational database can be used to simplify numerous administrative functions such as financial transactions (including billing, payment and account settlements), auditing, quality assurance, risk management and statistical analysis reporting.

III Data and Database Structures

See FIGS. **2**, **3**, **4**, **5**, and **6**.

A Overview

The presently preferred embodiment of this invention utilizes object-oriented programming. C++ language is used.

The invention utilizes numerous classes. The fundamental classes of objects used in the system are: field objects **200** (FIG. **2**), record objects **220** (FIG. **3**) and update objects **240** (FIG. **4**).

These objects are generated at all POS stations. They are then distributed to other POS stations and to PDCs, utilizing their own self-contained identification tags and using the rule sets which exist in various parts of the system.

For demonstration and discussion purposes, each of these objects can be depicted in the form of a "table"; although, in the present embodiment, the individual objects and collections of these objects, do not actually exist in traditional "table" form.

Traditional "table" structure, such as that used in relational databases, implies rigid columns and rows with fixed field and record sizes. However, in the present invention, each of the objects is of variable length; and all objects are stored in the databases utilizing just as much space as they need. Space is not wasted.

Furthermore, in the present embodiment, data is not identified by the fixed row and column it is stored in; rather it is stored economically in as little space as possible and it is identified using a pointer system which indicates the position and the length of the stored data package.

B Field Objects **200**

See FIG. **2**.

Field objects are the smallest objects. In the present embodiment, each field object consists of the field type or data type identifier, the field length and the field value. The data type identifier and the field length both describe properties of the field value.

The data type identifier indicates the category of information that the field value falls under, such as: (1) a CPT code identifier of a laboratory test, (2) a "status" indicator, or (3) a "result" indicator.

The field length indicates the amount of storage space that the field value requires.

The field value is the actual value of the data that is being identified, such as: (1) the actual numbers of the CPT code, (2) the actual status of this test, such as the fact that this is a "final result" or (3) the actual result of the test, such as the hematocrit value is "40."

Field type, field length and field value can all be considered column headings of a field "table." Each row in the "table" describes a certain property of the data that is being identified. The entire "table" can be considered a "collection of fields objects" **210** and that collection indicates the basic information that is known about that particular item of data at that time.

In this embodiment, field objects do not exist on their own, but only exist within record objects.

C Record Objects **220**

See FIG. **3**.

In the present embodiment, a record object consists of a record type identifier, a unique identifier and a collection of fields.

The record type identifier indicates the category of information that the related collection of fields represents, such as: laboratory test ordered, laboratory test result, X-ray test ordered, X-ray test result, etc.

The unique record identifier used in this preferred embodiment is a time stamp. It is the time in seconds measured from midnight Jan. 1, 1970, GMT.

The collection of field objects has been described above. Again, the field value size is flexible, thus making the entire record object variable in size.

The record type, unique record identifier and collection of field objects can all be considered as column headings of a record "table." Each row in the "table," both generally and uniquely identifies the data that is contained in the collection of field objects column.

A record object adds a level of organization to collections of fields.

A record object is the form in which data persists in the various databases throughout the system.

An entire "table" of records is a "collection of records" **230** and it represents, in an organized fashion, all of the data contained in a patient's static medical file.

In this embodiment, record objects do not exist on their own, but only exist within update objects (described below) or within databases.

D Update Objects **240**

See FIG. **4**.

An update object adds a level of organization to a record object.

The update object essentially wraps identification and processing information around a single record object and becomes the dynamic form of that record object. The update object contains the processing tags that guide each record object from its point of origin to its intended destination database(s) and also the tags that indicate the type of

updating process that is to be accomplished when the record arrives at its destination database(s).

The update object is a key element of this preferred implementation. In conjunction with the processing rules that reside throughout the system, the update object allows distributed databases to be updated independently, without the need of creating or accessing a masterfile. It allows the updating process to be completed automatically without the need of human intervention. It also assures the accurate propagation of update information throughout the system. Each update object persists until it has been notified that the information it contains has successfully reached its intended destination(s).

In this embodiment, the update object consists of: an indication of its own length **241**, a unique patient identifier **242**, a unique update object identifier **243**, at least a single record object **220**, identification tags of the intended destination(s) of this update object (routing tags) **244**, the update object type identifier (database modification tags) **245**, acknowledgment flags **246** and a variable number of audit fields **247**.

Each update object contains an indication of its own length **241**. This allows for conservation of space throughout the system.

Since the update object is dynamic and moves through the system, it must contain a unique patient identifier **242**. The present embodiment utilizes the PDC's unique serial number for this purpose. Other patient identifiers are possible.

This embodiment uses an update time stamp, similar in form to the record object time stamp and an identifier of the source POS station as the unique update object identifiers **243**. Other unique identifiers could also be used.

Each update object contains at least a single record object **220** as described previously.

One purpose of the update object is to identify which of the distributed databases in the system this particular record object should be directed to; and this task is accomplished using the identification tags of the intended destination(s) **244**. Using these tags and the rule sets that exist in various parts of the system, the update object routes itself to the appropriate independent databases.

Furthermore, when the update object arrives at the destination databases, it interacts with the rule sets contained there and deposits its record object in the databases according to its update type identifier **245**.

In the present embodiment, the update type identifier indicates the type of processing action that is intended when the update object reaches its destination database(s), such as: (a) add the enclosed record object to the collection of records, (b) delete a record that is already in the database, or (c) replace a record object that is already in the database with this new record object.

Whereas record objects are intended to be persistent, update objects are transient. They exist for the purpose of directing the processing of the record object they contain. When that purpose has been achieved, the update object, as an entity, can be deleted. The acknowledgment flags **246** are this system's method of determining how long a particular update object needs to persist in any particular location. Essentially, acknowledgment flags are indicators of all of the specific destinations that a particular update object must reach.

In operation, it is a copy of each update object that is actually propagated through the system. Each update object persists at its own originating station; and a copy of that object persists at each subsequent station along its propagating route.

The original object and the copies, all persist, until they receive notification, in the form of feedback acknowledgments, that the appropriate copies have been successfully received at all locations in the system for which the original update object was intended.

As acknowledgments are received from each intended location, the flag **246** for that location is inactivated. When all acknowledgments have been received and all flags inactivated, the update object is deleted from that particular part of the system, because it is no longer needed there.

Therefore, in a static state, a particular patient's medical file will only include a collection of record objects **230**. There will not be a collection of update objects **250**. This will indicate that all of this patient's medical data has been successfully distributed to all of the independent databases that need it.

For accuracy and security purposes, each update object contains a varied number of fields with auditing tags **247**. In the present embodiment, combinations of time stamps and an identifier of the machine that generated the update object are used for audit functions. Other identifiers and audit protocols are possible.

E Databases **260**

See FIGS. **5** and **6**.

In the present embodiment, object-oriented databases exist in each PDC **103**, in each POS station **122**, and in the administrative services system **152**. In addition, the presently constructed administrative services system contains a relational database **154**, using a commercially available database manager.

The object-oriented databases allow rapid storage and retrieval of data in an application specific form. They store data in a format that is efficient and appropriate for patient encounters at medical point-of-service locations.

The flexibility in size of the field, record and update objects allows economical use of space.

In the present embodiment, the distributed databases contain collections of record objects **230** (FIG. **3**) and collections of update objects **250** (FIG. **4**). These are primarily accessed by a key patient identifier, which presently is a unique patient serial number. The system also allows data access via demographic information, code numbers, data type identifiers and the like.

All of these object-oriented databases are flexible in size and format. They do not have the rigid structure and space restrictions of the traditional database models, such as the table structure of the relational database, with its rigid rows and columns, or records and fields.

Although the field, record and update objects do not actually exist in table form in the preferred embodiment, an "embedded table" format **260** can be used to describe the concepts of the present system.

Referring to FIG. **4**, a collection of field objects can be depicted as a "table." The column headings are field type, field length and field value. The rows identify a particular item of data. This "table" exists embedded within a record object.

A collection of record objects can be depicted as another "table," with the column headings of record type, unique record identifier and collection of field objects "table." Each row is a single record object. This collection of records "table" can be embedded in the overall database "table."

A collection of update objects can be depicted as another "table," with the column headings of: update length **241**, unique patient identifier **242**, unique update object identifier **243**, a record object "table" containing its collection of field objects "table" **220**, identification tags of intended destina-

tions **244**, update type identifiers **245**, acknowledgment flags **246** and audit fields **247**. Each row is a single update object. This collection of updates "table" can be embedded in the overall database "table," just the same as the collection of records "table."

The database "table" has column headings of unique patient identifier, collection of records "table" and collection of updates "table." Each row contains the entire medical file of a particular patient.

As mentioned previously, in the present embodiment, the administrative services system also contains a relational database and a database conversion system for coupling the object-oriented and the relational databases.

The purpose of the relational database is to include its generally known management and administrative advantages in the present system.

IV Technical Structure

See FIG. **6**.

A Portable Data Carrier **100**

The presently preferred portable data carrier is a microprocessor and memory-based smart card, that conceptually has four principle subsystems: a communication manager **101**, a file manager **102**, a file system (database) **103** and a security manager **104**.

The invention is designed to use the smart card command set by which commands are input and output through the serial communication port via the communication manager.

Smart card requests include security requests and file requests which are directed to the security manager and file manager respectively. The file manager will not allow memory read/write operations to the internal file system database unless authorized by the security manager. Authorizations are the result of bi-directional communications between the security manager and the file manager.

In the presently preferred embodiment, all patient information data is stored as a collection of record objects in the file system database. Although other structures are possible, the present system utilizes electronically erasable programmable read-only memory (EEPROM), because of its ability to retain information even when external power is turned off.

B Point-of-service Stations **110**

In the presently preferred embodiment, the subsystems of the POS stations are: the user interface **111**, the database manager **116**, the database **122**, the patient manager **123**, the PDC manager **124**, the communication manager **128**.

(1) The user interface **111** generates and initiates the propagation of record objects and update objects. It also generates the user display screens that the POS station operator sees.

The user interface contains: a controller module **112**, a view module **113** and a data model generation module **114**. It accesses the system graphical interface of the operating system **115**.

The controller module **112** responds to the PDC presence signals transmitted to it and initiates the user interface's response to the PDC's presence. It is also the principle connection to the presentation manager of the operating system.

The data model generation module **114** constructs the record objects and update objects with the appropriate tags attached, sends the update object to the controller module, which then transmits the update object to the rest of the system.

In the presently preferred embodiment, much of the processing that takes place within the user interface is invisible to the user. The user interface is able to communicate through the controller module with the rest of the system, while concurrently sending displays to the presentation manager for the station operator to view. A separate view module **113** is provided for that purpose.

Information appropriate for presentation to the station operator is selected from the controller module and the data model generation module, assembled into the appropriate display and transmitted to the presentation manager of the operating system **115**. The presently preferred embodiment operates in a fully concurrent fashion, so that the controller module and the data generation module can construct data objects, communicate with the PDC and handle data routing and updating functions while the view module concurrently displays information to the station operator.

This offers an important advantage in the present embodiment because communication with the station operator and communication with the PDC are typically the lowest throughput links in the system. The present configuration takes advantage of this arrangement, allowing many data processing tasks to be performed concurrently while the system is reading and writing to the PDC and also while the station operator is interacting with the system through the user screen. During typical operation, the station operator can interact with the user screen, inputting information about the patient, or about the diagnosis or procedures to be performed, without noticing any degradation in system performance as the PDC is concurrently being read and updated.

(2) The POS database manager **116** controls access to the database. It contains: a record object manager **117**, an update object manager **118**, a data engine **119**, an index engine **120** and codes tables subsystem **121**.

The index engine coupled to the data engine provides access to the database. As mentioned previously, the access is via serial numbers, demographic information, code numbers, data type and the like.

The data engine **119** controls the storage and retrieval of data from the database storage subsystem. The data engine is coupled to both the record object manager **117** and the update object manager **118**. Collectively, these two object managers contain the rule sets by which medical information objects are processed according to the processing tags embedded within the data objects.

The codes table subsystem **121** can contain numerous types of codified information. The present system includes standard medical CPT and ICD-9 code tables, as well as lists of authorized physicians and list of authorized medications.

(3) The POS database **122** is object-oriented. It is flexible in size. It stores and retrieves data according to key identifiers, which include unique patient serial numbers, demographic information, code numbers and data type. Data is stored as collections of record objects **230** (FIG. 3) and as collections of update objects **250** (FIG. 4).

(4) The patient manager **123** is the coordinator of the POS station. It communicates with the user interface **111**, the database manager **116**, the PDC manager **124** and the communication manager **128**. It contains major rule sets relating to data processing, such as routing update objects and modifying databases. These rule sets will be described later.

(5) The PDC manager **124**, contains; a PDC presence monitor **125** and a PDC database manager **126**.

The PDC presence monitor detects the presence of a PDC when it is installed in the read/write port.

The PDC database manager handles access and security functions. It assures that the PDC conforms to the physical

specifications of the system and that the PDC is not fraudulent or defective. It also copies the record objects from the PDC database. It then retrieves any update objects that are stored in the POS database and applies these updates to the PDC collection of records, thus making the PDC records the most current in the system. Copies of this updated collection of records are then sent to both the PDC and the POS databases.

In order to save space and time, the PDC database manager performs the necessary processing steps to determine which fields need to be updated, so that only those fields are written to the PDC.

The PDC database manager is resident within the POS station and has greater throughput capacity than the PDC. While selective updating of the PDC is presently preferred for throughput reasons, the invention can be implemented in alternate ways, such as downloading a complete copy of the updated collection of records.

(6) The communication manager **128** controls the POS station's bidirectional communication with the switching station. In the presently preferred embodiment, this communication takes place using asynchronous modems, although any standard communication system could be used. The communicated data is encrypted for security purposes. The communication manager **128** is able to both initiate and receive calls over a communication channel.

The communication manager interacts with the application layer **129**, that is in turn connected to the successive layers of the open system's OSI architecture, namely presentation layer **130**, session layer **131**, transport layer **132**, network layer **133**, physical **134** and data link **135** layers. These layers ultimately communicate with the transmission medium.

C Switching Station **140**

In the presently preferred embodiment, the switching station provides a conduit for keeping the various independent databases current. It contains rule sets for routing update objects between POS stations, according to the routing tags contained in the update objects. This is an alternate communication channel to the PDC-POS connection and may be utilized when the PDC is not directly available as the data transport medium.

In the present system, the switching station temporarily stores a local copy of each update object that it transmits. The local copy remains in memory at the switching station until all destination POS stations have acknowledged successful receipt of the update object. It is then deleted from the switching station memory.

In this embodiment, the switching station also sends a copy of each update object to the administrative services system. Although this connection provides access to some administrative services, such as data backup, auditing and billing, the integrity of the network does not depend on this connection. The system functions well without needing to access a masterfile.

In the presently preferred embodiment, the switching station contains two subsystems: a communication manager **141** and an update manager **142**.

The communication manager **111** is configured to communicate bidirectionally with each POS station. In the present embodiment, this is achieved via asynchronous modems, although other communication channels are possible. For security purposes, the transmitted data is encrypted. The communication manager **141** is able to both initate and receive calls over the communication channel.

The communication manager also handles bidirectional communication with the administrative services system. Local or wide area networks can both be utilized depending on the geographic distribution of the system. In the present embodiment, TCP/IP protocol is used with ISDN and ethernet connections. Other protocols and connections can certainly be used.

The update manager **142** contains the rule sets for routing update objects between POS stations. Although it can be configured otherwise, in the present embodiment, the POS station of the patient's primary physician and the administrative services system both receive a copy of every update object pertaining to that patient. Copies of an update object are also sent to the ordering physician and to other various POS stations as may be designated on the update objects destination tags.

For example, when a consultant physician orders a laboratory test, the patient goes to the laboratory and has the test performed. The laboratory's POS station generates the update object containing the result of the test. That update object is: (1) stored in the laboratory's database and (2) transmitted to the switching station. From the switching station, it goes to: (3) the consultant physician's office, (4) the primary physician's office and (5) the administrative services station. From the primary physician's office or the consultant's office, the result is transmitted to: (6) the patient's PDC.

In this example, when the above process has been completed, the test result will have been successfully and automatically propagated to six independent locations, without needing to access a central database or masterfile, and without requiring the POS stations to be physically connected to each other.

Furthermore, the update object remains "alive" in the system, until assurances, in the form of acknowledgments, have been received, indicating that the record object it contains has successfully reached all of its designated databases.

D Administrative Services System **150**

In the presently preferred embodiment, the administrative services system consists of: a communication manager **151**, an object-oriented database **152**, a database conversion system **153**, a commercially available relational database **154** and "customer" services **155**.

(1) The communication manager **151** controls communication with the switching station as described above. Direct communication between the administrative services system and the POS stations is possible, but is not presently configured, mainly for security purposes.

(2) The presently preferred object-oriented database **152** is application specific. It is configured according to the "embedded table" architecture described previously. It contains a key patient identifier, collections of record objects and collections of update objects.

It essentially contains a duplication of each of the PDC and POS databases, with the added feature that all update objects persist here indefinitely, primarily for auditing purposes.

Although the presently preferred distributed database architecture is relatively fail-safe on its own because it distributes the data independently throughout the system and does not rely on a central station or masterfile, the administrative services system's database can be used to backup the distributed PDC and POS databases when necessary.

(3) The database conversion system **153** translates the information from the object-oriented structure to a relational database structure. This is accomplished by individually selecting record objects from the object-oriented database and depositing them in fixed field and record relational tables.

(4) In the presently preferred embodiment, a relational database architecture, IBM's DB/2, **154** is included to accommodate interaction with a plurality of external systems and services.

It allows the present invention to interact easily and efficiently via widely used standard protocols and query languages. It facilitates communication with healthcare providers, managers, payers and researchers. It allows the present invention to provide services, such as the "customer" services described below.

(5) "Customer" services **155** are the ancillary management-type services provided by this system to patients, healthcare providers, managers, payers and researchers. These services include, but are not limited to, data backup, billing, payment, account settlement, medical and financial auditing, report generation, quality control and risk management.

V Describing Data Flow via Processing Rules

See FIGS. **7**, **8**, **9**, **10**, **11** and **12**.

A An Overview of the Processing Rules

In the presently preferred embodiment, each patient's medical file is kept current at numerous independent databases by routing medical data through the system via update objects that interact with strategically placed rule sets.

The update objects are generated at all POS stations and in the administrative services system.

The general rules for processing update objects are located within each POS station, in the switching station and in the administrative services system. The general processing rules, as shown in FIGS. **7** and **8**, are distributed as follows:

User Interface Ill

Generate update object

Send update object to patient manager

Request patient record from this POS database

Patient Manager **123**

Concurrently update PDC and POS databases

Bring PDC records up to date

Send updated PDC records to this POS database

Get patient records from this POS database for user interface

Propagate update object that was generated in this user interface

Add new update object to this station's database

Store update objects in queue

Intermittently send update objects to the communication manager

Send update objects to PDC manager

Propagate update object that was received from the switching station

Add update object to this station's database

Sort update objects by patient ID

Sort update objects by type

Send record objects to this station's database according to the above sorting

Database Manager **116**

Add update object to collection of update objects

Store update objects until acknowledgments are received

Modify database by adding, deleting, or replacing record objects

PDC Manager **124**

Notify patient manager of PDC presence

Copy records from the PDC

Receive updates from this POS station's database

Apply updates to copy of PDC records

Send updated records to PDC and this station's database

Communication Manager **128**

Send update objects to switching station

Receive update objects from switching station

Switching Station **140**

Receive update objects from POS stations and administrative services system

Route update objects to designated POS stations

Route update objects to administrative services system

Store update objects until acknowledgments are received

Send update objects to POS stations and administrative services system

B Specific Processing Rules Within a POS Station

In the present embodiment, within each POS station, each update object **240** (FIG. **4**) is generated in the user interface **111**. From there, it is routed through the patient manager **123** to the database manager **116**, the PDC manager **124** and the communications manager **128**. See FIG. **6**. This routing is accomplished by following the rules which define the interactions among these various subsystems.

The rules themselves can be divided into sets based on the several different routing functions that the POS station can accomplish. These functions are: (1) concurrently updating the PDC and POS databases when a PDC is presented for service (FIG. **9**), (2) propagating an update object that was generated in this POS station (FIG. **10**) and (3) propagating an update object that was received from the switching station (FIG. **11**). Each of FIGS. **9–11** show, through a series of sequentially numbered steps, the order in which the rules are implemented.

(1) Concurrently updating the PDC and POS databases when a PDC is presented for service (FIG. **9**):

1	Insert PDC in POS station.
2	PDC manager copies the records from the PDC.
3	PDC manager notifies the patient manager that the PDC is present.
4	Patient manager requests updates from the database manager.
5	Database manager sends the updates from the database to the patient manager.
6	Patient manager sends the updates from the database to the PDC manager.
7	PDC manager acknowledges processing of updates from the patient manager.
8	PDC manager applies updates to copy of PDC records.
9	PDC manager sends updated records to PDC.
10	Patient manager requests patient records from the database manager.
11	Database manager sends patient records from the database to the patient manager.
12	Patient manager requests the updated patient records from the PDC manager.
13	PDC manager sends the updated patient records to the patient manager.
14	The patient manager applies the updated records from the PDC manager to the patient records from the database.
15	Patient manager sends the updated records to the database manager.
16	Database manager sends the updated records to the database.
17	Patient manager notifies its "get patient records for user interface" section that this station's database records have been updated.
18	PDC manager notifies the user interface that a PDC is present.

-continued

19	User interface requests the patient records from the patient manager.
20	Patient manager waits for notification that this station's database has been updated.
21	Patient manager requests the updated records from the database manager.
22	Database manager sends the updated records from the database to the patient manager.
23	Patient manager sends the updated patient records to the user interface.
24	User interface receives the patient records for interface use.

At the end of this series of transactions, both the PDC database **103** and the POS database **122** are identical and current. The two databases have updated each other; and the updated records are ready for use at the user interface **111**.

Since this embodiment utilizes a multitasking operating system, the POS station operator can interact with the user interface with no perceived delay, while the PDC and POS databases are interrogating and updating each other.

(2) Propagating an update object that was generated at this POS station (FIG. **10**):

1	The user interface generates a new update object.
2	The user interface sends the update object to the patient manager.
3	Patient manager routes the update object to three of its subsections; see steps (4), (13) and (16).
4	The patient manager sends the update object to the database manager.
5	The database manager adds the update object to the collection of update objects in the database.
6	The patient manager sorts the update objects by type (add, delete, replace).
7	The patient manager sends an "add this record object" message to the database manager.
8	The database manager adds the record object to the database.
9	The patient manager sends a "delete this record object" message to the database manager.
10	The database manager deletes the record object from the database.
11	The patient manager sends a "replace this record object" to the database manager.
12	The database manager replaces the record object in the database.
13	The patient manager sends the update object to the PDC manager.
14	The PDC manager applies the updates to the PDC manager's copy of the PDC records.
15	The PDC manager sends the updated records to the PDC.
16	The patient manager stores the update objects until they are requested by the communication manager.
17	The communication manager intermittently requests updates from the patient manager.
18	The patient manager sends update objects to the communication manager.
19	The communication manager sends update objects to the switching station.

At the end of this series of transactions, a new update object **240** has been generated, stored in the POS database **122**, transferred to the PDC database **103** and sent to the switching station **140**. By utilizing a multitasking operating system, all of these transactions can essentially occur simultaneously.

(3) Propagating an update object that was received from the switching station (FIG. **11**):

1	The communication manager of the POS station receives an update object from the switching station.
2	The communication manager sends the update object to the "apply update objects to this station's database" section of the patient manager.
3	The patient manager sorts the update objects by patient identification.
4	The patient manager sends the update objects to the database manager based on patient identification.
5	The database manager adds the update objects to the collection of updates in this station's database based on patient identification.
6	The patient manager sorts the update objects by type (add, delete, replace).
7	The patient manager sends an "add this record object" message to the database manager.
8	The database manager adds the record object to this station's database.
9	The patient manager sends a "delete this record object" to the database manager.
10	The database manager deletes the record object from this station's database.
11	The patient manager sends a "replace this record object" to the database manager.
12	The database manager replaces the record object in this station's database.

At the end of this series of transactions, an update object **240** that has been received from the switching station **140**, has been deposited in this POS station's database **122**. The database is modified appropriately; and if so designated, the update object persists until it is successfully transmitted to a PDC database **103**.

C Processing Rules for Routing an Update Object Through the Entire System (FIG. **12**):

In the present embodiment, each update object is generated and propagated within a POS station according to the above rules. The update object is then routed to the switching station for propagation through the rest of the system.

The switching station acknowledges receipt of every update object from each POS station. It then routes all update objects to the administrative services system. For functions such as data backup, system security and auditing, a copy of every update object is retained in an administrative services database indefinitely.

The switching station also routes each update object to the POS stations designated on the update objects destination tags. In the present embodiment, all update objects will at least be routed to the physician who ordered the procedure that generated the update object and to the patient's primary physician.

For example, if a consultant physician orders a laboratory test, the destination tag on the update object that contains the test result will indicate that the update should be sent to that consultant. The rule set in the switching station will read the update object and recognize that the physician who ordered the test is a consultant and not the patient's primary physician; so it will also route the update object to the primary physician.

The switching station stores a copy of each update object until it receives an acknowledgment from each of the destination POS stations that the update object has been successfully received. When all acknowledgments have been received, the update object is deleted from the switching station.

The following are the rules that define the propagation of an update object through the entire system (FIG. **12**):

1	The user interface in the initial POS station generates an update object.
2	The user interface sends the update object to the patient manager.
3	The patient manager routes all update objects and acknowledgments.
4	The patient manager sends the update object to the database manager.
5	The database manager sends the update object to the database.
6	The collection of record objects within the database is updated.
7	The update object is temporarily stored until all acknowledgments are received.
8	The patient manager sends the update object to the PDC manager.
9	The PDC manager sends an acknowledgment (A) to the patient manager that it has received the update.
10	The patient manager sends that acknowledgment (A) to the database manager.
11	The database manager sends that acknowledgment (A) to the update object in the database.
12	The PDC manager applies the update object to its copy of the PDC records.
13	The PDC manager sends the updated records to the PDC.
14	The patient manager sends the update object to the communication manager.
15	The communication manager sends the update object to the switching station.
16	The switching station sends an acknowledgment (B) to the communications manager that it received the update.
17	The communications manager sends that acknowledgment (B) to the patient manager.
18	The patient manager sends that acknowledgment (B) to the database manager.
19	The database manager sends that acknowledgment (B) to the update object in the database.
20	The update object is deleted from the database since it has received the appropriate acknowledgments (A) and (B).
21	The switching station sorts the update object according to designated POS station destinations.
22	The switching station stores update objects until all acknowledgments have been received.
23	The switching station sends the update object to designated POS stations.
24	The POS station sends acknowledgment (C) of receipt of the update object to the switching station.
25	The switching station receives the acknowledgment (C).
26	The POS station updates its own database just like the initial POS station.
27	The POS station stores the update object until all acknowledgments have been received.
28	The POS station updates the PDC database when a PDC is presented.
29	The switching station sends the update object to the administrative services system.
30	The administrative services system sends acknowledgment (D) of receipt of the update object to the switching station.
31	The switching station receives acknowledgment (D) from the administrative services system.
32	The update object is deleted from the switching station because it has received the appropriate acknowledgments (C) and (D).
33	The administrative services system updates its own database.

At the end of this series of events, the patient's PDC database **103**, as well as all designated POS databases **122** and the administrative services system database **150** are all synchronized and current. See FIG. **6**. All record objects **220** (FIG. **3**) have been deposited appropriately and acknowledged. All update objects **240** (FIG. **4**) have been deleted from the system. And this has all been accomplished without needing to access a masterfile.

We claim:

1. A computer system for maintaining the currency of data in distributed databases, comprising:

a data communication network;

a plurality of physically separate databases, each of said databases including means for communicating with said data communication network, said databases collectively defining said distributed databases;

a processor having interface for supplying an input instruction to modify the contents of the distributed databases;

said processor being coupled to said data communication network;

said processor being operable to generate an update object in response to said instruction and to place said update object in said data communication network;

said update object having a self-contained processing tag for causing said update object to be intelligently routed along said data communication network to at least one of said plurality of databases and for causing said one of said plurality of databases to automatically modify its contents in accordance with said input instruction;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network.

2. The system of claim **1** wherein said data communication network comprises a system employing a portable data carrier having memory for storing and transferring data among said plurality of databases.

3. The system of claim **1** wherein said data communication network comprises a telecommunication network.

4. The system of claim **1** wherein said data communication network comprises in combination:

a system employing a portable data carrier having memory for storing and transferring data among said plurality of databases; and

a telecommunication network.

5. The system of claim **1** wherein said data communication network is coupled to a routing processor responsive to said processing tag in intelligently routing said update object along said data communication network.

6. The system of claim **1** wherein said processing tag of said update object comprises a data structure for storing a destination datum for causing said update object to be intelligently routed along said data communication network.

7. The system of claim **1** wherein said data communication network is coupled to a routing processor and wherein said processing tag of said update object comprises a data structure for storing a destination datum that is accessed by said routing processor in causing said update object to be intelligently routed along said data communication network.

8. The system of claim **1** wherein at least one of said databases includes a database processor responsive to said processing tag in modifying the contents of its database.

9. The system of claim 1 wherein said processing tag of said update object comprises a data structure for storing an operation datum based on said input instruction for use in automatically modifying the contents of at least one of said databases.

10. The system of claim 1 wherein at least one of said databases includes a database processor and wherein said processing tag of said update object comprises a data structure for storing an operation datum based on said input instruction that is accessed by said database processor in modifying the contents of said one of said databases.

11. The system of claim 1 wherein said data communication network is coupled to a routing processor having an associated memory for storing a routing rules set.

12. The system of claim 1 wherein said processing tag of said update object comprises a data structure for storing a destination datum that is used according to predefined rules to cause said update object to be intelligently routed along said data communication networks.

13. The system of claim 1 wherein said processing tag of said update object comprises a data structure for storing a destination datum that is used according to predefined rules to cause said update object to be intelligently routed to a selected one of said databases.

14. The system of claim 1 wherein said data communication network is coupled to a routing processor having an associated memory for storing a routing rules set and wherein said processing tag of said update object comprises a data structure for storing a destination datum that is accessed by said routing processor and used in accordance with said routing rules to cause said update object to be intelligently routed along said data communication network.

15. The system of claim 1 wherein said data communication network includes a routing processor having an associated memory for storing a routing rules set and wherein said processing tag of said update object comprises a data structure for storing a destination datum that is used according to said routing rules to cause said update object to be intelligently routed to a selected one of said databases.

16. The system of claim 1 wherein at least one of said databases includes a database processor and an associated memory for storing an operation processing rules set.

17. The system of claim 1 wherein said processing tag of said update object comprises a data structure for storing an operation datum based on said input instruction that is used according to predefined rules to automatically modify the contents of at least one of said databases.

18. The system of claim 1 wherein at least one of said databases includes a database processor and an associated memory for storing an operation processing rules set and wherein said processing tag of said update object comprises a data structure for storing an operation datum based on said input instruction that is accessed by said database processor and used in accordance with said operation processing rules to automatically modify the contents of at least one of said databases.

19. The system of claim 1 wherein said data communication network includes a routing processor having an associated memory for storing a routing rules set and wherein said processing tag of said update object comprises a data structure for storing a destination datum that is accessed by said routing processor and used in accordance with said routing rules to cause said update object to be intelligently routed to at least a selected one of said databases, and

wherein at least said selected one of said databases includes a database processor and an associated memory for storing an operation processing rules set and wherein said processing tag of said update object comprises a data structure for storing an operation datum based on said input instruction that is accessed by said database processor and used in accordance with said operation processing rules to automatically modify the contents of said selected one of said databases.

20. A computer-implemented method of maintaining the currency of data in distributed databases consisting of a plurality of physically separate databases, comprising:

receiving an input instruction corresponding to a request to modify data in said distributed databases;

using said input instruction to generate an update object that includes a self-contained processing tag;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network;

conveying said update object to at least a selected one of said plurality of databases using said processing tag to cause said update object to be intelligently routed to said selected one of said databases;

further using said processing tag to cause said selected one of said databases to automatically modify its respective contents in accordance with said input instruction.

21. The method of claim 20 further comprising employing a portable data carrier to convey said update object by storing the contents of said update object in said portable data carrier and physically transporting said portable data carrier between said selected databases.

22. The method of claim 20 further comprising using a telecommunication network to transmit said update object between said selected databases.

23. The method of claim 20 further comprising using a data communication network that employs, in combination, a portable data carrier and a telecommunication network and wherein said conveying step is performed by at least one of the following methods:

(a) by storing said update object in said portable data carrier and physically transporting said portable data carrier between said databases and

(b) by transmitting said update object over said telecommunication network.

24. The method of claim 20 wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated processor to write to a processing tag a datum indicative of a destination database to which the update object is intelligently routed.

25. The method of claim 20 wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated

processor to write to a processing tag a datum to specify a selected one of a plurality of data manipulation processes.

26. The method of claim **20** wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated processor to read said processing tag and to intelligently route said update object to a second one of said plurality of databases in accordance with said processing tag.

27. The method of claim **20** wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated processor to read said processing tag and to route said update object to a communication network.

28. The method of claim **20** wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated processor to read said processing tag and to route said update object to a routing processor coupled to a communication network.

29. The method of claim **20** wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises using said associated processor to read said processing tag and to modify the contents of said first database in accordance with said processing tag.

30. The method of claim **20** further comprising conveying said update object over a data communication network to a routing processor.

31. The method of claim **20** further comprising:

conveying said update object over a data communication network to a routing processor; and

using said routing processor to route said update object to at least a second one of said plurality of databases over said data communication network.

32. The method of claim **20** wherein at least a first one of said databases includes an associated processor and wherein said method further comprises storing a routing rules set in a memory addressed by said associated processor and using associated processor to access said routing rules set and said processing tag to cause said update object to be routed along said data communication network.

33. The method of claim **20** wherein said data communication network includes an associated processor and wherein said method further comprises storing a routing rules set in a memory addressed by said associated processor and using said associated processor to access said routing rules set and said processing tag to cause said update object to be intelligently routed to a destination database.

34. The method of claim **20** wherein at least a first one of said plurality of databases has an associated processor and wherein said method further comprises storing an operation processing rules set in a memory addressed by said associated processor and using said associated processor to access said rules set and said processing tag and to modify the contents of said first database.

35. An information system for maintaining the currency of computerized records, comprising:

a first processor with associated first memory for storing a first database of computerized records;

a second processor with second memory for storing a second database of computerized records;

said first and second memories being disposed at physically separate locations;

a smart card having an embedded third processor and associated third memory for storing a third database of computerized records;

said first and second processors each having a port for interfacing with said smart card;

said smart card being:

operable as a client and server to said first and second databases;

physically transportable between said first and second databases; and

operable to propagate information between said first and second databases such that the currency of computerized records is maintained in said first, second and third databases;

wherein said first processor generates an update object for routing an element of information to said second database;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network.

36. The information system of claim **35** wherein at least one of said first and third processors operate on both first and third databases to mutually update both first and third databases.

37. The information system of claim **35** wherein at least one of said second and third processors operate on both second and third databases to mutually update both second and third databases.

38. The information system of claim **35** wherein at least one of said processors generates an update object carried by said smart card.

39. The information system of claim **35** wherein said first processor generates an update object for routing an element of information to said second database, said update object including a processing tag to identify at least a selected one of a plurality of data processing operations; and

wherein said second processor operates on the computerized records stored in said second database using said element of information in accordance with said processing tag.

40. A self-updating computer-implemented database system for storing elements of information comprising:

a computer-implemented system for generating an update object that stores an element of information and that includes a processing tag for specifying at least one of a plurality of predefined data manipulation processes and for causing said update object to be intelligently routed to at least one destination;

a second database with associated second processor for receiving said update object;

a second database with associated second processor for receiving said update object;

said update object further having an object-oriented data structure that defines independently created field

objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network,

said first processor being responsive to the processing tag of said update object to:

(a) modify the contents of said first database in accordance with the data manipulation process specified by said processing tag;

(b) store said update object in said first database; and

(c) convey said update object to said second database in accordance with the destination specified by said processing tag;

said second processor being operative to:

(i) modify the contents of said second database in accordance with the data manipulation process specified by said processing tag; and

(ii) send an acknowledgment of receipt of said update object to said first processor;

said first processor being operative to initiate deletion of said update object from said first database in response to receipt of said acknowledgment from said second processor.

41. The system of claim **40** wherein said computer-implemented system generates said update object in response to input from a user of said database system.

42. The system of claim **40** wherein said second processor is further operative to store said update object in said second database.

43. The system of claim **40** wherein the system includes a third database with associated third processor and wherein said second processor is further operative to convey said update object to said third processor.

44. The system of claim **40** further comprising a data communication network and wherein said first processor conveys said update object to said second processor over said communication network.

45. The system of claim **44** wherein said data communication network comprises a system employing a portable data carrier having memory for storing said update object.

46. The system of claim **44** wherein said data communication network comprises a telecommunication network.

47. The system of claim **44** wherein said data communication network comprises in combination:

a system employing a portable data carrier having memory for storing said update object; and a telecommunication network.

48. The system of claim **44** wherein said data communication network is coupled to a routing processor for reading said processing tag and conveying said update object to at least said second database.

49. The system of claim **40** wherein said first and second databases are disposed at physically separate locations.

50. The system of claim **40** wherein said update object includes means for storing an identification datum that functions as a database key.

51. An information system for maintaining the currency of computerized records, comprising:

a first processor with associated first database of computerized records;

a second processor with associated second database of computerized records;

said first and second databases being disposed at physically separate locations;

a portable data carrier having a third processor and associated third database of computerized records;

said first and second processors each having a port for interfacing with said portable data carrier;

said portable data carrier being operable as a client and server to said first and second databases and physically transportable being said first and second processors to define a first communication channel that is operable to propagate information between said first and second databases;

at least one of said first and second processors having a routing rules set forth for causing at least one of said first and second processors to propagate information between said first and second databases over a second communication channel;

whereby said first and second communication channels collectively operate such that currency of computerized records is maintained in said first, second and third databases;

wherein said first processor generates an update object that is propagated over at least one of said first and second communication channels;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network.

52. The information system of claim **51** wherein said portable data carrier is a smart card that includes said third processor and said third database.

53. The information system of claim **51** wherein the first database stores an update object containing a database modification processing tag;

wherein at least one of the first and third processors causes at least one of the first and third databases to be initially modified according to the processing tag and then at least one of the first and third processors updates the other of said first and third databases based on the information in said initially modified database;

and wherein at least one of the second and third processors updates the second database based on the information contained in third database upon the portable data carrier being physically transported to said second database.

54. The information system of claim **51** wherein the first processor generates an update object containing a routing

tag and database modification tag, the first processor stores the update object in the first database and sends the update object along said second communication channel to the second processor based on said routing tag and said second processor modifies the second database based on said database modification tag.

55. The information system of claim **51** wherein said first processor has a processing rules set accessed by said first processor to generate an update object for routing an element of information to said second database.

56. The information system of claim **51** wherein said first processor has a first processing rules set accessed by said first processor to generate an update object for routing an element of information to said second database, said update object including a processing tag to identify at least a selected one of a plurality of data processing operations; and

wherein said second processor has a second processing rules set accessed by said second processor to cause said second processor to operate on the computerized records stored in said second database using said element of information in accordance with said processing tag.

57. The information system of claim **51** wherein said second database includes an administrative services system.

58. An information system for maintaining the currency of computerized records in distributed databases, comprising:

a first database with associated first processor;

a second database with associated second processor;

said first and second databases being disposed at physically separate locations;

a first communication channel comprising a portable data carrier having a third database with associated third processor, the portable data carrier being operable as a client and server to said first and second databases and physically transportable between said first and second processors to propagate information between said first and second databases;

a second communication channel accessible by said first and second processors;

a first system for collectively updating said first, second and third databases, wherein:

(a) at least one of said first and third processors is operable to mutually update said first and third databases; and

(b) at least one of said second and third processors is operable to mutually update said second and third databases;

a second system for collectively updating said first and second databases, wherein:

(a) said first processor generates an update object having a processing tag for specifying at least one of a plurality of predefined data manipulation processes and for specifying at least one destination;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update object;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network,

(b) said first processor modifies the contents of said first database in accordance with the data manipulation process specified by said processing tag;

(c) said first processor propagates said update object to said second processor along said second communication channel in accordance with the destination specified by said processing tag;

(d) said second processor modifies the contents of said second database in accordance with the data manipulation process specified by said processing tag;

whereby the currency of computerized records in said first, second and third databases are maintained current.

59. The system of claim **58** wherein said portable data carrier is a smart card that includes said third processor and said third database.

60. The information system of claim **58** wherein said first processor includes a user interface and wherein said first processor generates said update object based on information supplied through said user interface.

61. The information system of claim **58** wherein the first database stores an update object containing a database modification processing tag;

wherein at least one of the first and third processors causes at least one of said first and third databases to be initially modified according to the database modification processing tag and then at least one of the first and third processors updates the first database based on the information in the initially modified database;

and wherein at least one of the second and third processors updates the second database based on the information in the third database, upon the portable data carrier being physically transported to said second database.

62. The information system of claim **58** wherein the first processor generates an update object containing a routing tag and database modification tag, the first processor stores the update object in the first database and sends the update object along at least one of said first and second communication channels to the second processor based on said routing tag and said second processor modifies the second database based on said database modification tag.

63. The information system of claim **58** wherein said second database includes an administrative services system.

64. A self-updating, computer-implemented distributed database system for storing elements of information comprising:

a computer system for generating and storing data objects that include:

(a) a record object for storing an element of information;

(b) an update object for defining a relationship with at least one associated record object, said update object storing a processing tag;

said update object further having an object-oriented data structure that defines independently created field objects and record objects, said field objects and said field objects each having stored attributes that record information about processes performed on those objects;

said data structure encapsulating data for storing information independent of said distributed databases, said

data structure defining a nested, hierarchial relationship such that said field objects are encapsulated within said record objects and wherein said record objects encapsulated within said update objects;

said update object thereby being configured to automatically store data and to automatically store in said attributes an historic record of processes performed on said data as said update object is routed anywhere throughout said communication network,

said computer system further generating a database system that comprises a collection of record objects that define a persistent portion of the database and a collection of update objects that define a transient portion of the database;

the database system being responsive to said processing tag for automatically updating the persistent portion of said database;

the database system further including a feedback mechanism comprising a second update object for systematically purging said update objects from the transient portion of the database.

65. The database system of claim **64** wherein said record object includes a field object for storing said element of information.

66. The database system of claim **64** wherein said update object includes an acknowledgement tag accessed by said feedback mechanism in purging said update objects from the transient portion of the database.

67. The database system of claim **64** wherein said processing tag comprises a routing tag and a database modification tag.

68. The database system of claim **64** wherein said record object includes a record identification tag.

69. The database system of claim **64** wherein at least one of said record objects and said update objects employs a variable length data storage mechanism.

70. The database system of claim **69** wherein said variable length storage mechanism uses a pointer system for data storage and retrieval.

71. The database system of claim **64** wherein said database system includes a first database having a first processor and wherein said feedback mechanism uses said first processor to read the processing tag of said update object and to store said update object in the transient portion of the first database.

72. The database system of claim **64** wherein said database system includes a first database having a first processor and a second database having a second processor and wherein said feedback mechanism uses said first processor to read the processing tag of said update object and to route said update object to said second database in accordance with said processing tag.

73. The database system of claim **64** wherein said database system includes a first database having a first processor and a second database having a second processor and wherein said feedback mechanism uses said second processor to generate a second update object having a second processing tag.

74. The database system of claim **73** wherein said second processing tag is an acknowledgement tag.

75. The database system of claim **64** wherein said database system includes a first database having a first processor and a second database having a second processor and wherein said feedback mechanism uses said second processor to transmit a second update object having second processing tag to said first processor.

76. The database system of claim **64** wherein said database system includes a first database having a first processor and a second database having a second processor;

wherein said feedback mechanism uses said first processor to read the processing tag of a first update object and to store said first update object in the transient portion of the first database;

wherein said feedback mechanism uses said first processor to transmit said first update object to said second processor;

wherein said feedback mechanism uses said second processor to transmit a second update object having a second processing tag to said first processor in response to said first update object; and

wherein said feedback mechanism uses said first processor to read said second processing tag and to modify said first database by deleting said first update object from said first database in response to said second processing tag.

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US006305377B1

(12) **United States Patent**
Portwood et al.

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(45) **Date of Patent: *Oct. 23, 2001**

(54) **SYSTEM AND METHOD FOR IMPROVING COMPLIANCE OF A MEDICAL REGIMEN**

(76) Inventors: **Michael T. Portwood**, 1091 Plains - Port Hudson Rd., Zachary, LA (US) 70791; **John W. Portwood**, 10243 Winterhue Dr., Baton Rouge, LA (US) 70810

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation-in-part of application No. 08/766,584, filed on Dec. 12, 1996, now Pat. No. 5,950,630.

(51) **Int. Cl.**[7] **A61B 19/00**

(52) **U.S. Cl.** **128/897**; 128/904; 128/906; 705/2; 705/3

(58) **Field of Search** 128/897, 904, 128/906; 705/2, 3

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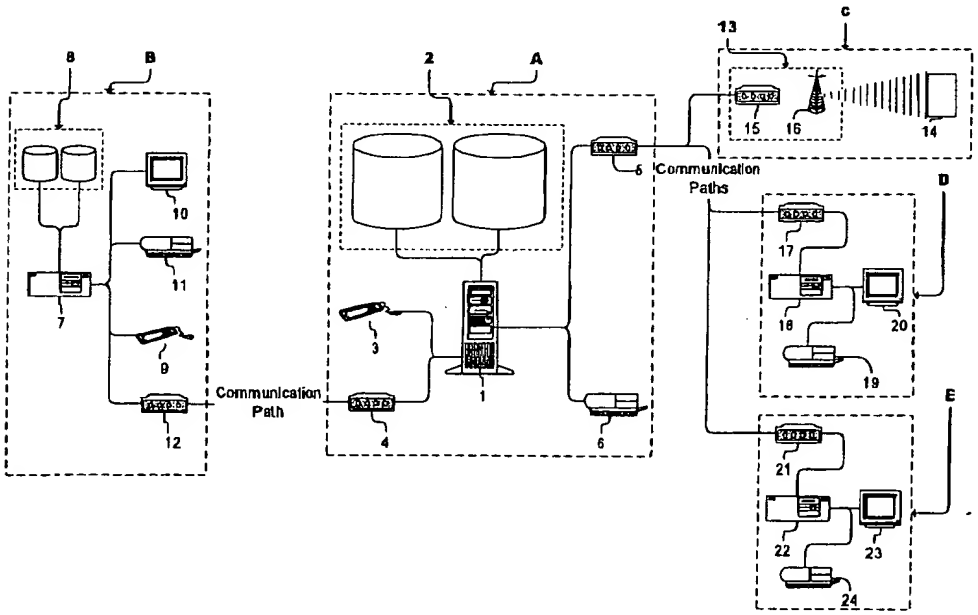
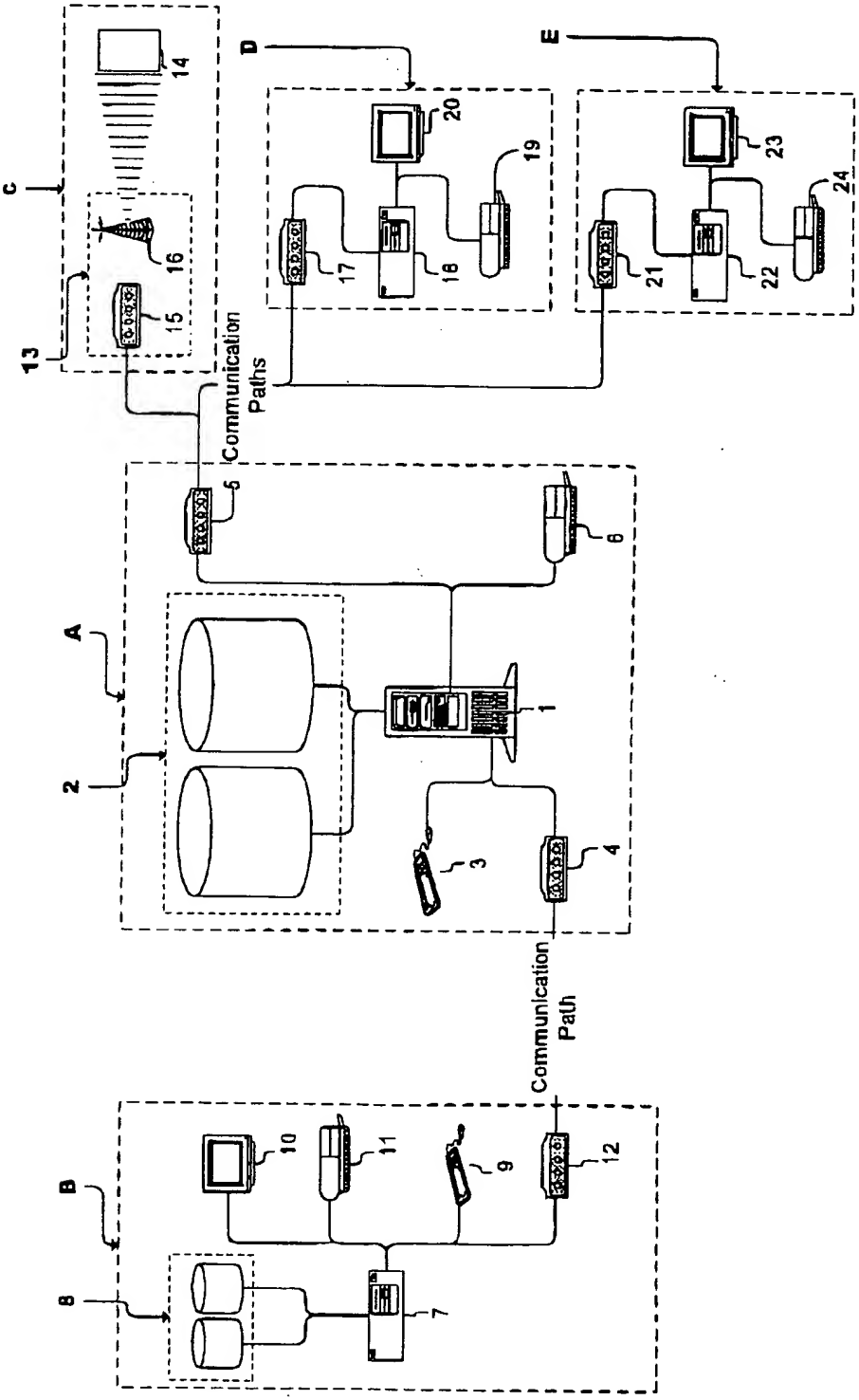
(57) **ABSTRACT**

A system and method for improving compliance by a patient with a medical regimen that has been prescribed to the patient wherein utilizing computer and electronic communication systems, patient data is compared to pharmaceutical data to verify prescribed drug dosage and prescribed medication duration are within acceptable limits, any abnormalities found by the comparisons are reported to the treating physician who may then alter the medical regimen before authorizing dispensing of the prescribed drugs and providing drug taking information to the patient, and upon authorization being issued, the patient is scheduled to receive reminder notifications prior to the prescribed time for the prescribed drugs to be administered, as well as automatically notifying the prescription distribution service to deliver the prescribed drugs to the patient, and notifying the payor service to pay for the prescribed drugs.

20 Claims, 13 Drawing Sheets

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Communication Paths
Communication Path

FIG. 1

FIG. 2

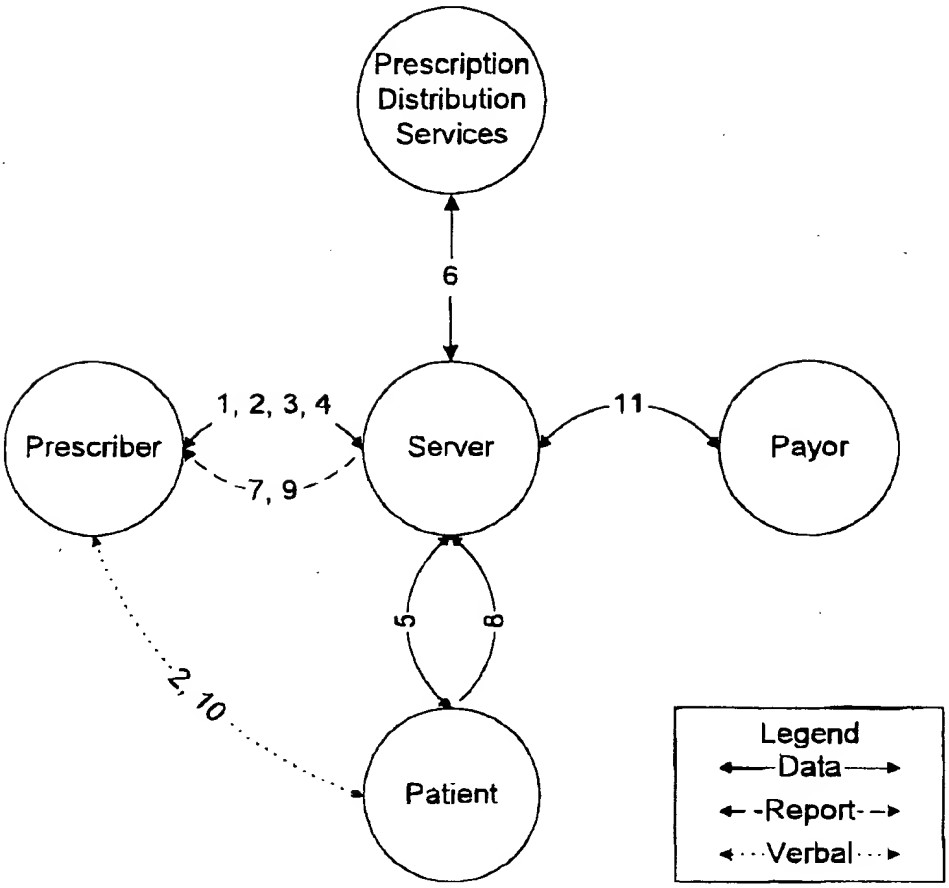

Prescription Distribution Services
6
Prescriber
1, 2, 3, 4
7, 9
Server
11
Payor
5
8
2, 10
Patient
Legend
Data
Report
Verbal

FIG. 3

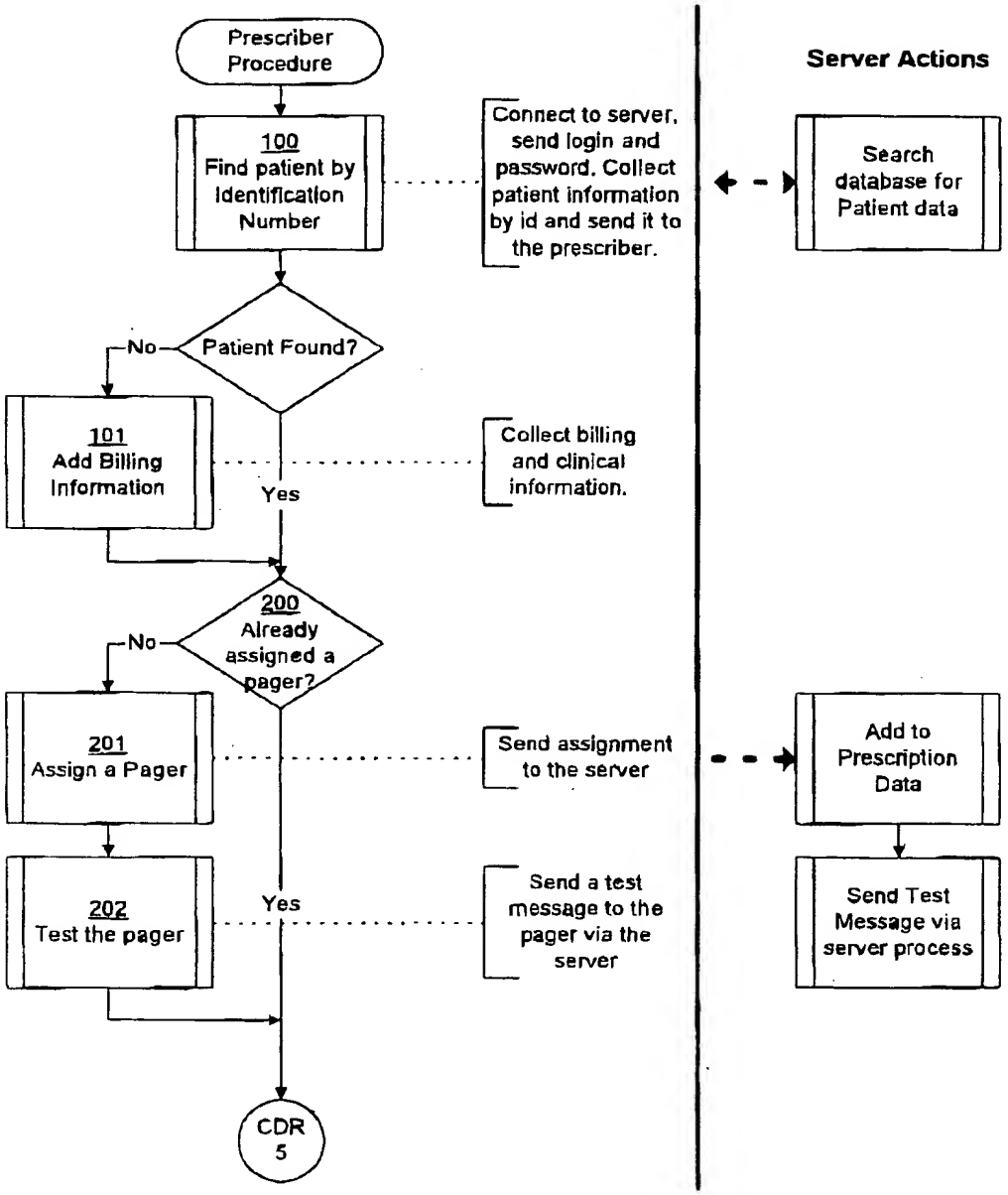

Prescriber Procedure
Server Actions
100 Find patient by Identification Number
Connect to server, send login and password. Collect patient information by id and send it to the prescriber.
Search database for Patient data
No
Patient Found?
101 Add Billing Information
Collect billing and clinical information.
Yes
200 Already assigned a pager?
No
201 Assign a Pager
Send assignment to the server
Add to Prescription Data
202 Test the pager
Yes
Send a test message to the pager via the server
Send Test Message via server process
CDR 5

FIG. 3 (Continued)

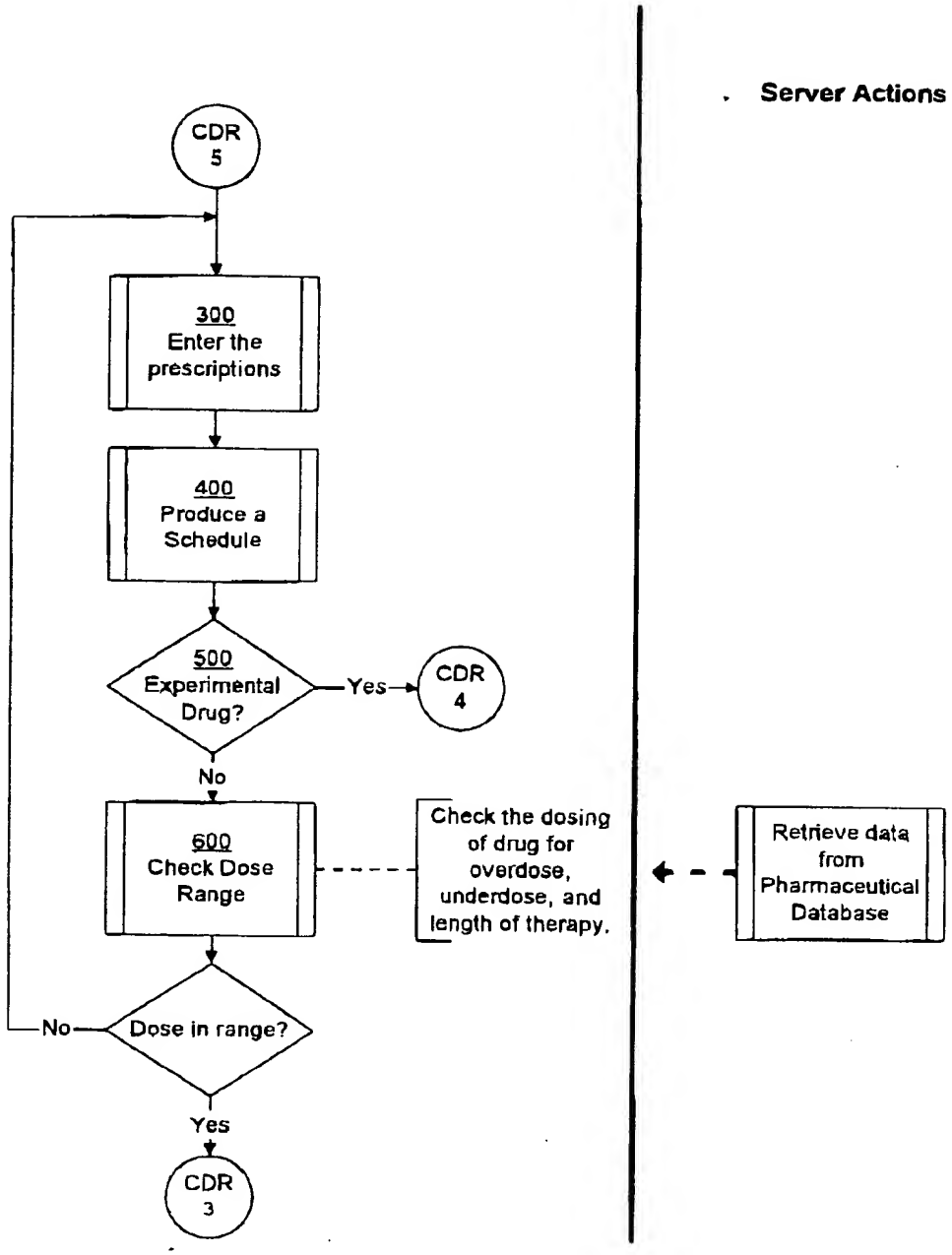


FIG. 3 (Continued)

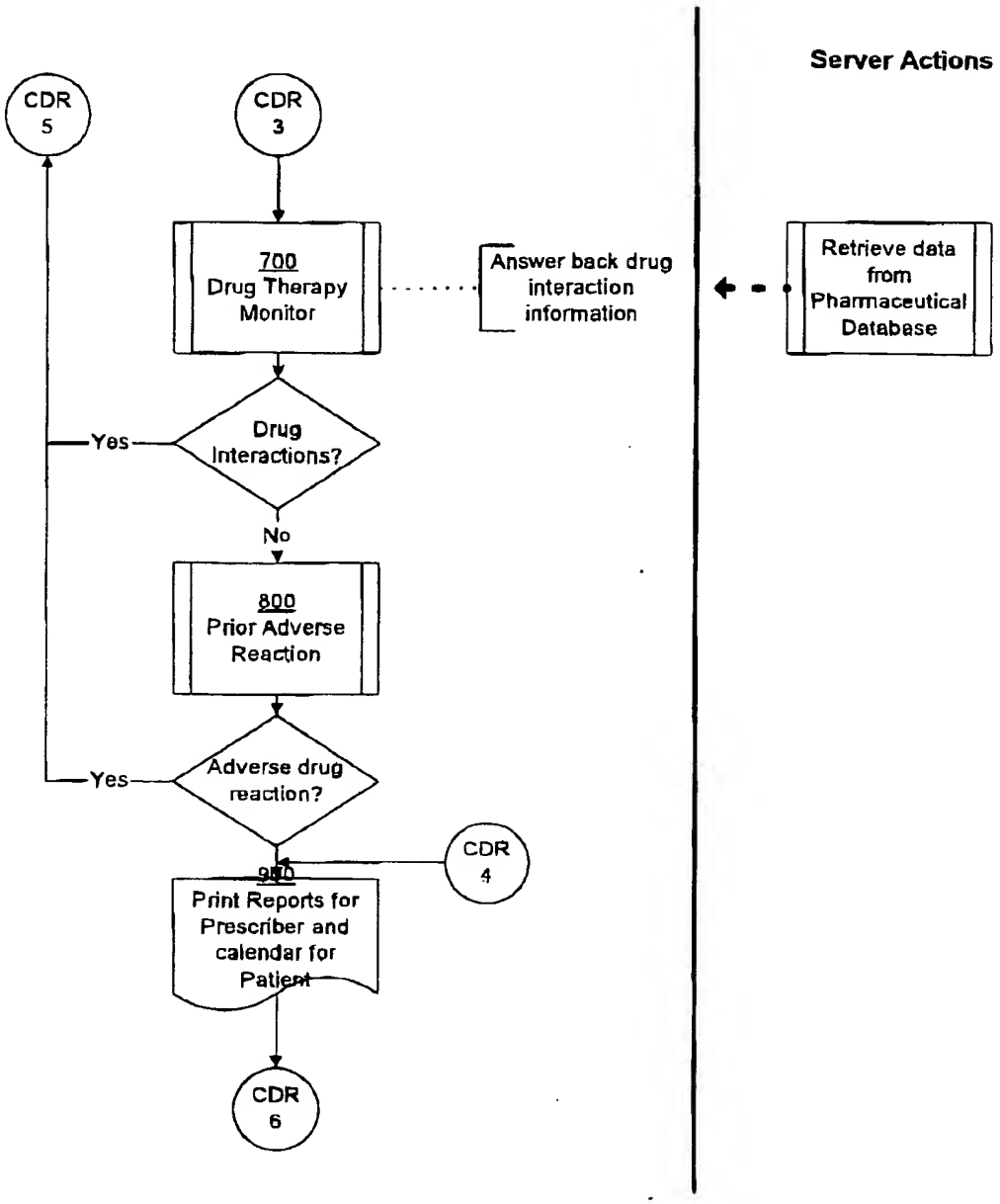


FIG. 3 (Continued)

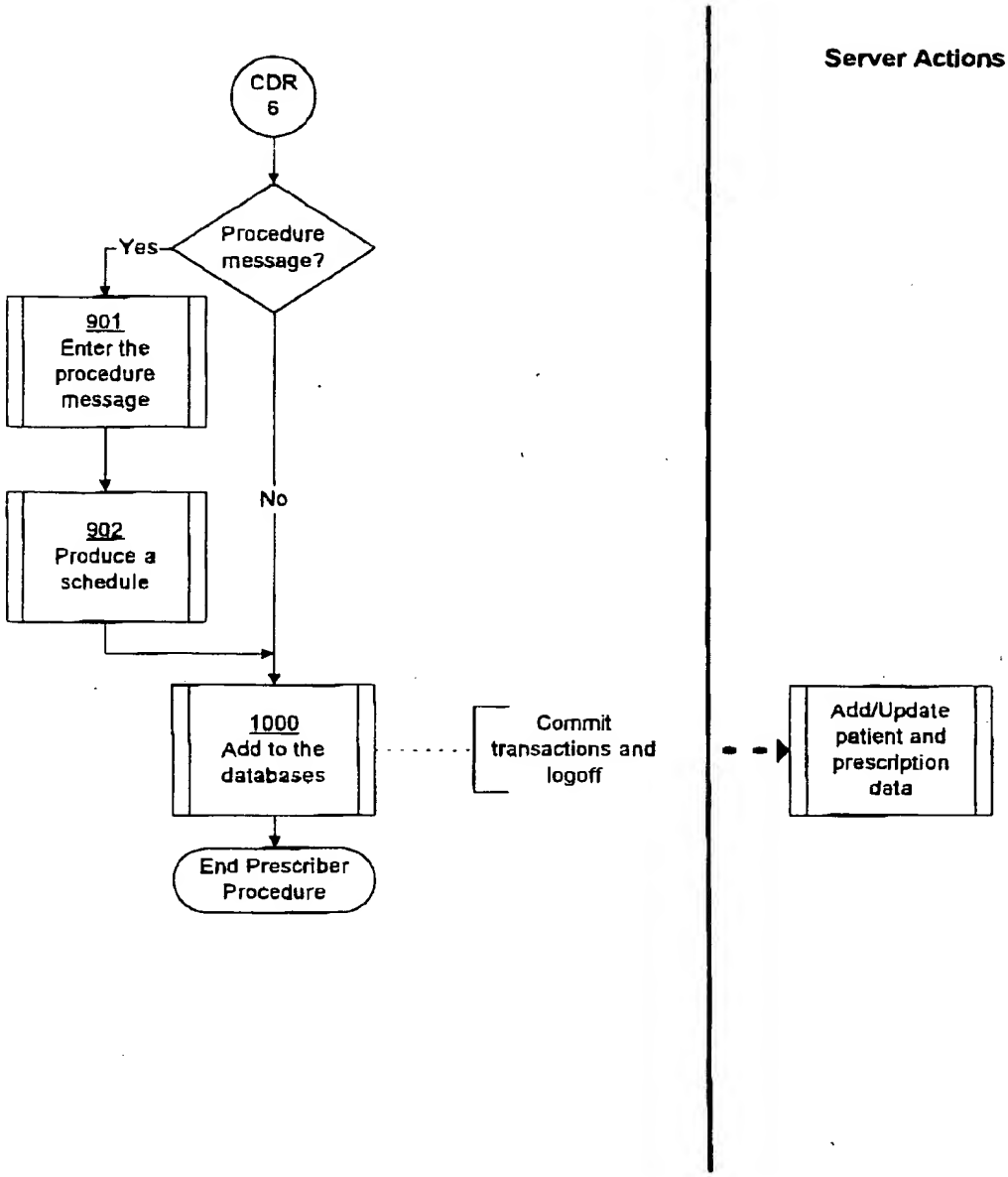


FIG. 3A

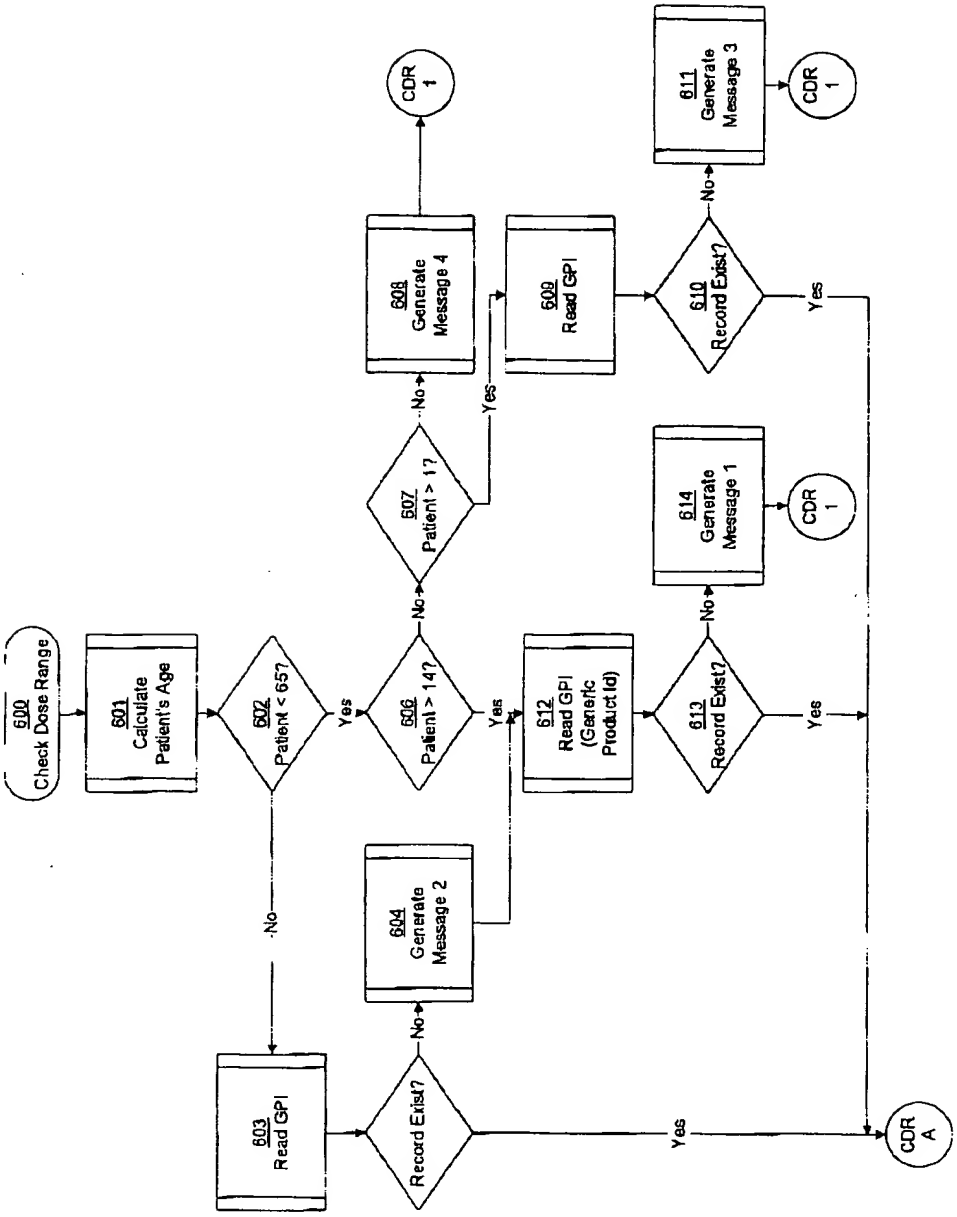

600 Check Dose Range
601 Calculate Patient's Age
602 Patient < 65?
603 Read GPI
604 Generate Message 2
606 Patient > 14?
607 Patient > 17
608 Generate Message 4
609 Read GPI
610 Record Exist?
611 Generate Message 3
612 Read GPI (Generic Product Id)
613 Record Exist?
614 Generate Message 1
Record Exist?
Yes
No
CDR 1
CDR A

FIG. 3A (Continued)

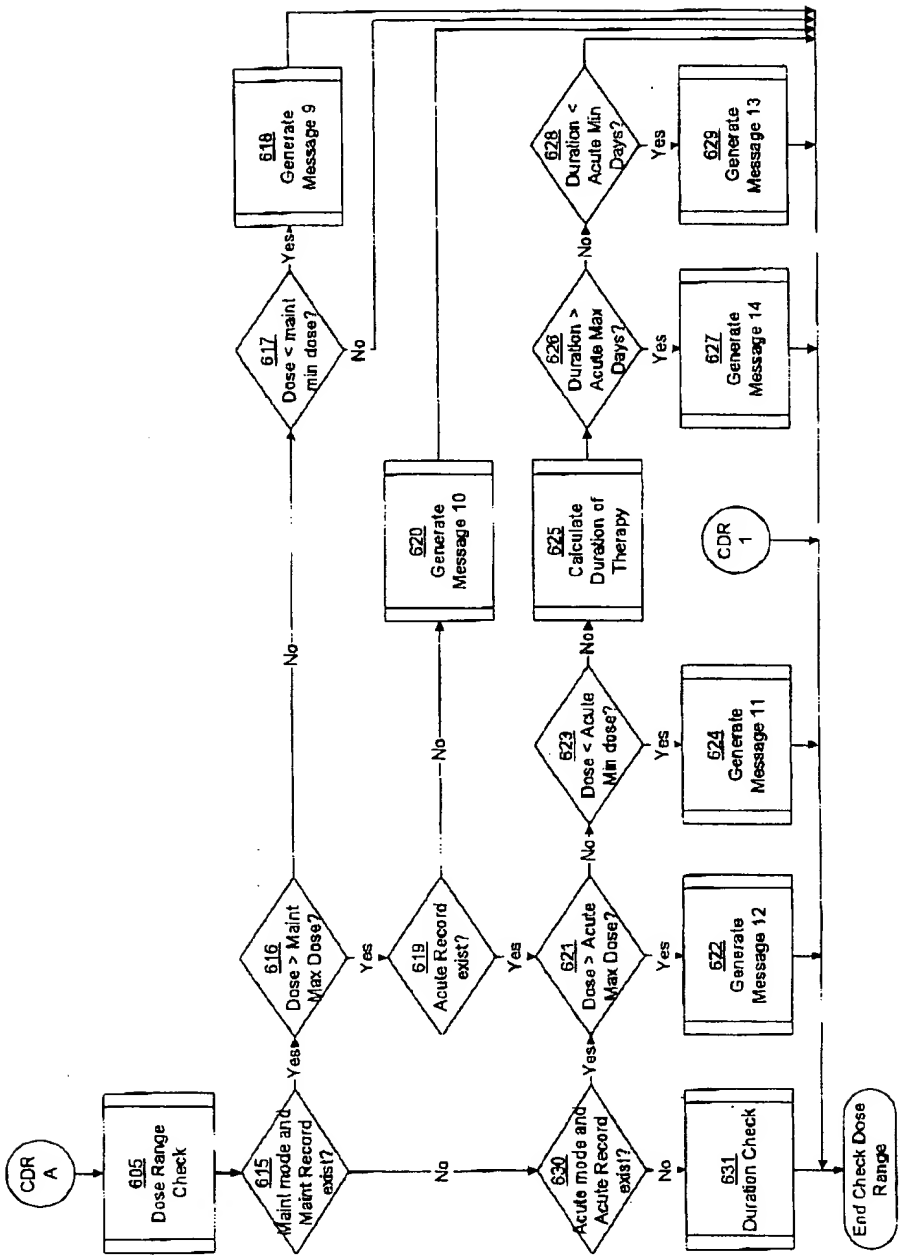


FIG. 3A-1

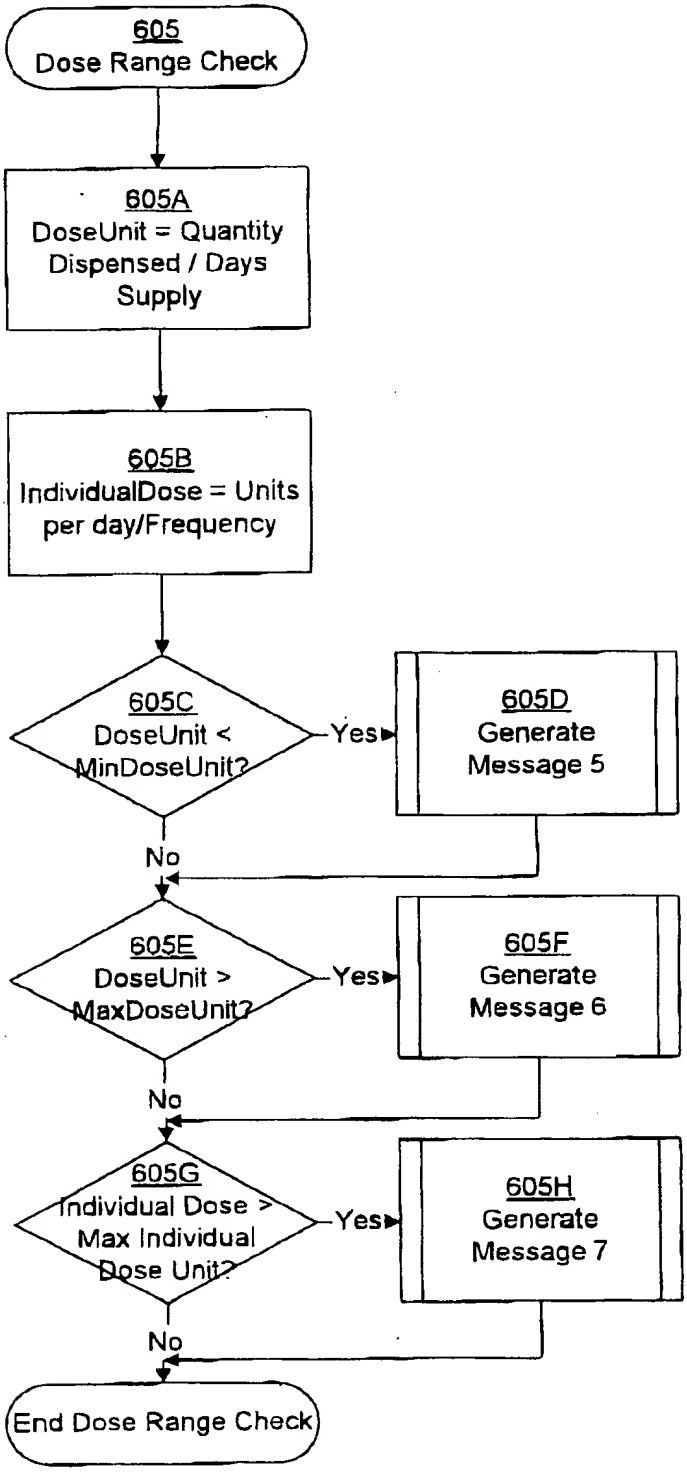

605
Dose Range Check
605A
DoseUnit = Quantity Dispensed / Days Supply
605B
IndividualDose = Units per day/Frequency
605C
DoseUnit < MinDoseUnit?
Yes
605D
Generate Message 5
No
605E
DoseUnit > MaxDoseUnit?
Yes
605F
Generate Message 6
No
605G
Individual Dose > Max Individual Dose Unit?
Yes
605H
Generate Message 7
No
End Dose Range Check

FIG. 3A-2

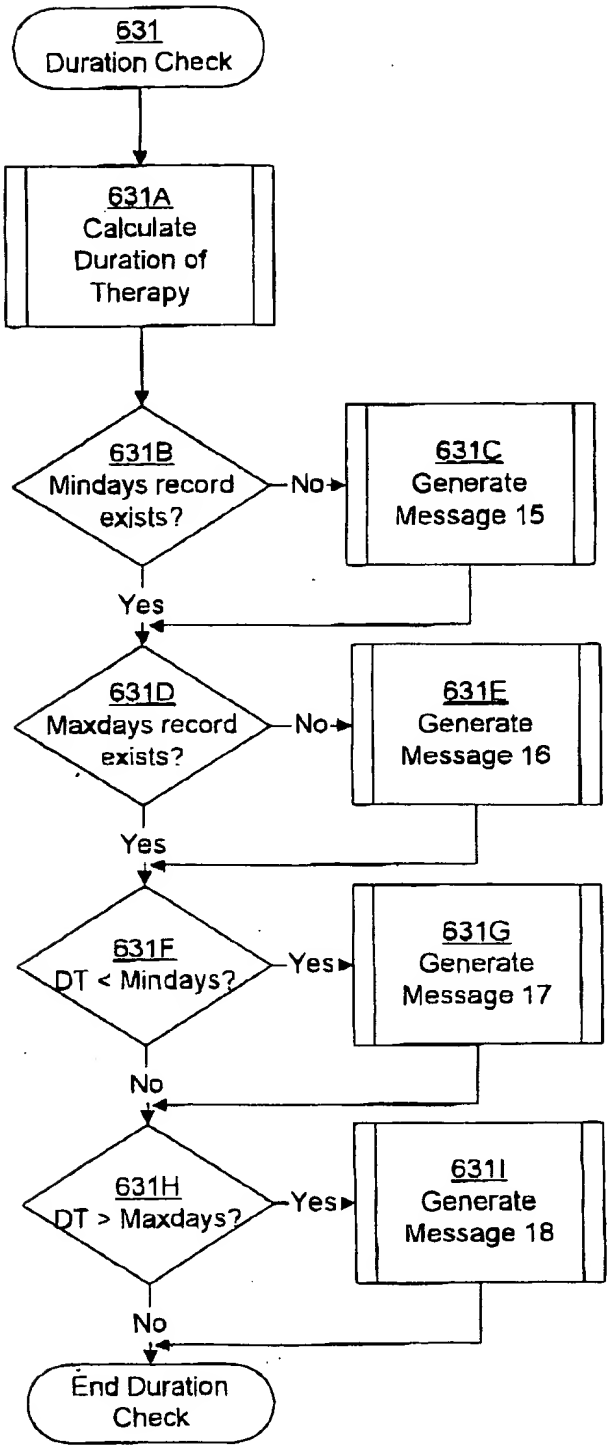

631
Duration Check
631A
Calculate Duration of Therapy
631B
Mindays record exists?
No
631C
Generate Message 15
Yes
631D
Maxdays record exists?
No
631E
Generate Message 16
Yes
631F
DT < Mindays?
Yes
631G
Generate Message 17
No
631H
DT > Maxdays?
Yes
631I
Generate Message 18
No
End Duration Check

FIG. 3B

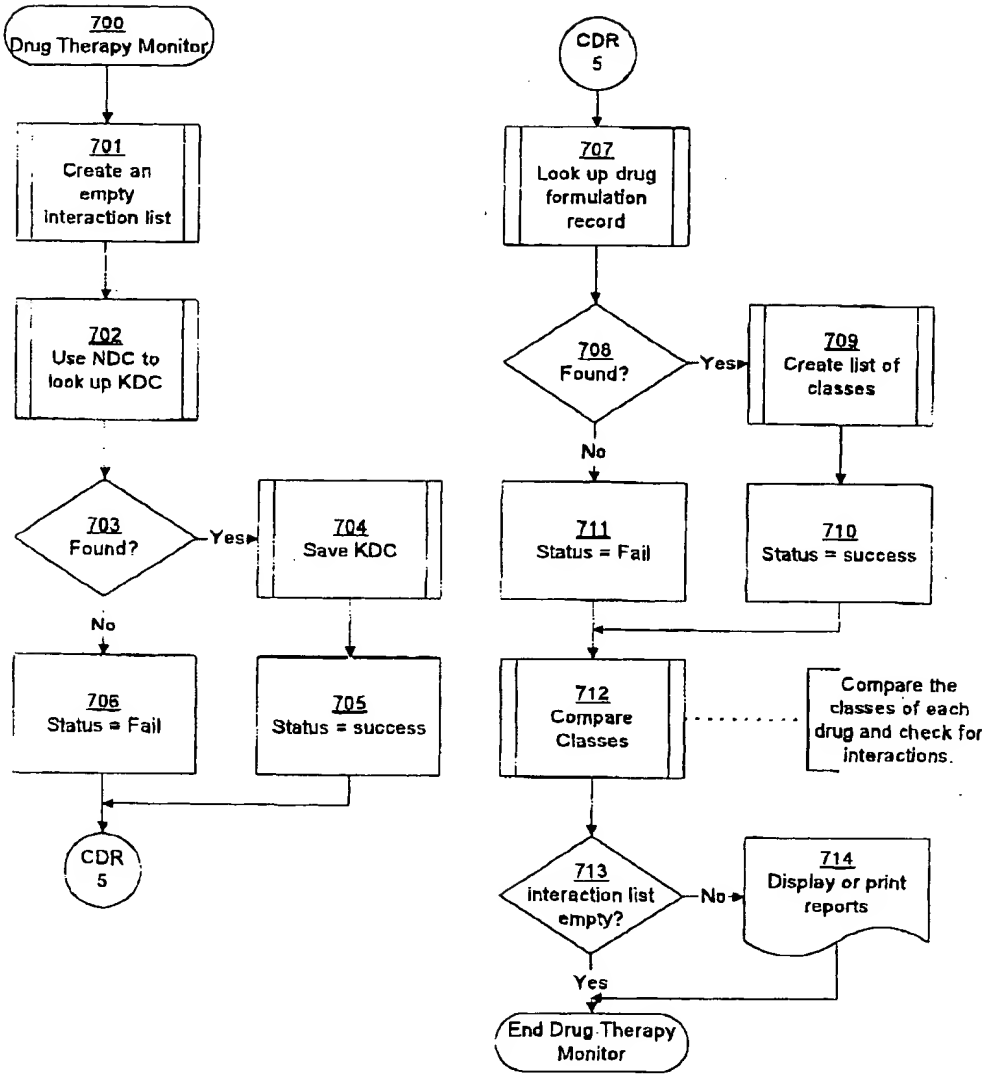

700
Drug Therapy Monitor
701
Create an empty interaction list
702
Use NDC to look up KDC
703
Found?
Yes
704
Save KDC
No
706
Status = Fail
705
Status = success
CDR 5
CDR 5
707
Look up drug formulation record
708
Found?
Yes
709
Create list of classes
No
711
Status = Fail
710
Status = success
712
Compare Classes
Compare the classes of each drug and check for interactions.
713
interaction list empty?
No
714
Display or print reports
Yes
End Drug Therapy Monitor

FIG. 4

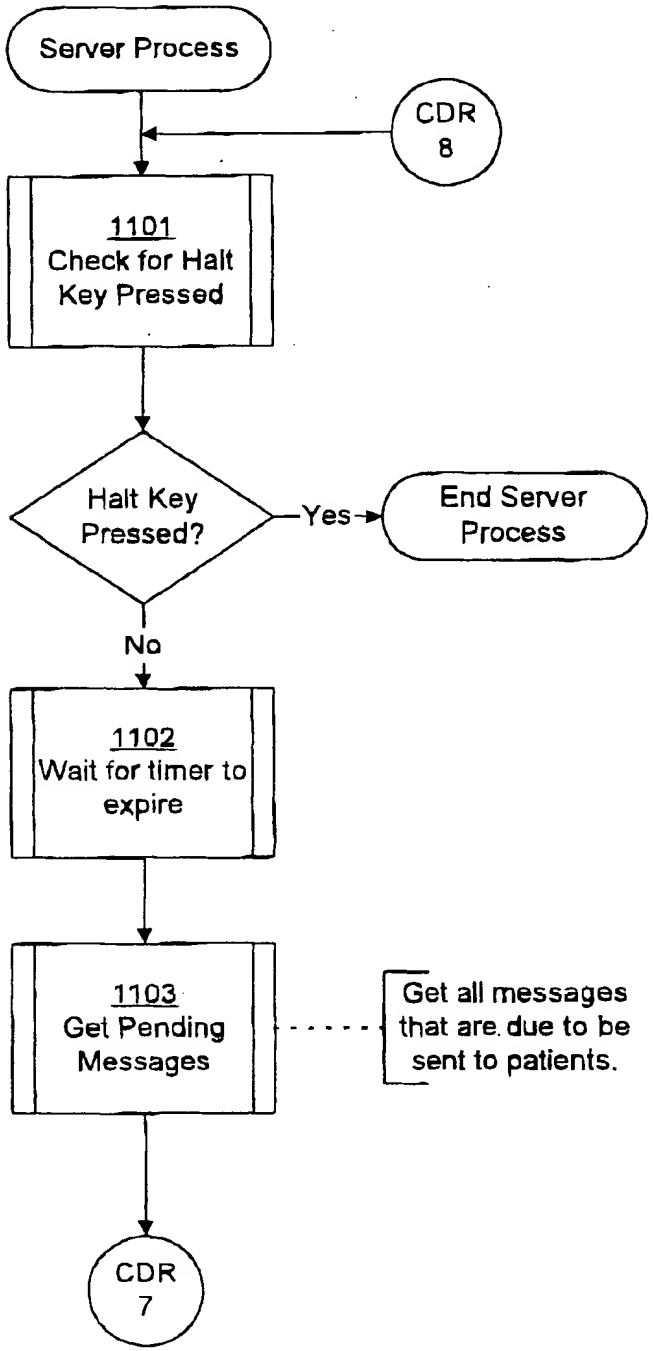
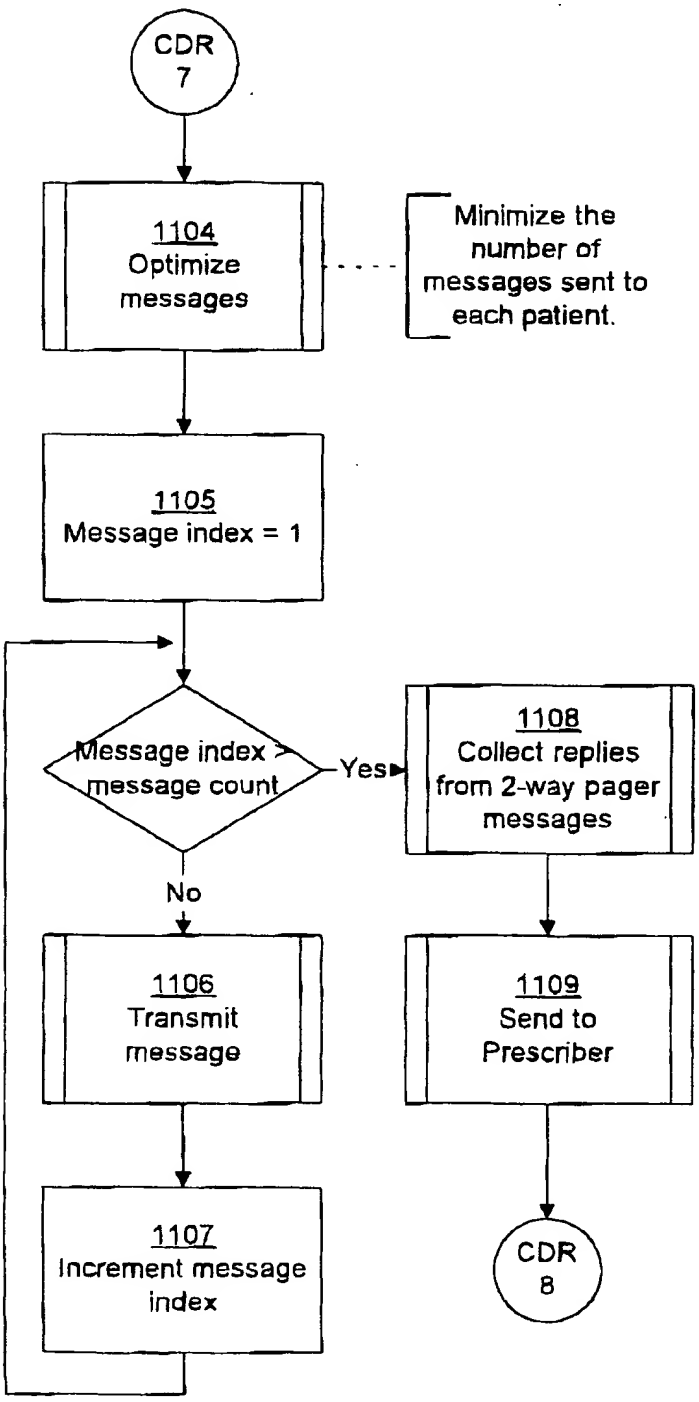

Server Process
CDR 8
1101 Check for Halt Key Pressed
Halt Key Pressed?
Yes
End Server Process
No
1102 Wait for timer to expire
1103 Get Pending Messages
Get all messages that are due to be sent to patients.
CDR 7

FIG. 4 (Continued)



SYSTEM AND METHOD FOR IMPROVING COMPLIANCE OF A MEDICAL REGIMEN

This is a continuation-in-part of U.S. application Ser. No. 08/766,584, filed Dec. 12, 1996 now U.S. Pat. No. 5,950, 630.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates in general to a system and method to facilitate compliance with a prescribed medical regimen and ensure integrity of the prescribed medical regimen, and more particularly, to a system and method to monitor the patient usage of drugs prescribed by the patient's physician and to verify that a prescription meets reasonable standards for the drug involved.

2. Prior Art

Noncompliance with a prescribed medical regimen, especially the inaccurate use of prescription drugs, is one of the main reasons for most outpatient treatment failure, as well as a cause of serious, life threatening medical complications.

The seriousness of the problem has been long recognized by the medical community. Numerous studies have been undertaken in an effort to identify the causes of noncompliance of a medication regimen. Various causes identified by these studies include forgetfulness, number of medications prescribed, unclear instructions or a lack of written instructions, side effects of the medication, cost of the medication, inconvenient or complex dosing schedules, lack of a primary health care physician, or lack of prescribed medication information given by the primary health care physician.

In attempts to overcome one or more of these causes, various equipment and systems have been devised. Examples of such systems can be seen in U.S. Pat. No. 4,695,954 which combines a special drug dispenser to be used by a patient in conjunction with a system which monitors the usage of the drugs by the patient. Another system is disclosed in U.S. Pat. No. 4,766,542 wherein patients are automatically contacted by automatic telephone dialing and voice synthesizing equipment to remind them that their prescriptions need to be refilled. U.S. Pat. No. 5,390,238 discloses a system linking the physician, pharmacists, patient, and care provider for the purpose of monitoring medication usage and patient wellness. However, the various prior art systems have proven to be workable only in controlled environments. Even then they leave unsolved many of the numerous other causes of noncompliance.

A second problem relating to medical regimens is lack of easy checking procedures to determine if a prescription complies with a recommended regimen. Currently, the U.S. FDA publishes a Generic Product Identifier (GPI) which is a listing of available drugs coded by their generic chemical composition and a National Drug Code (NDC) which is a listing of available drugs coded by their trade names. However, neither the GPI nor the NDC contain drug reaction information. There does exist a collection of studies which describe known reactions for certain drugs. This collection of studies is referred to herein as the Knowledge Base Drug Code (KDC). In addition, there are other studies which have established classes based on composition of the components which make up a drug. However, a compilation of this available information has not been assembled for easy use.

Thus, there remains in the medical community the need for a system, and a method of using the system, that better

ensures that a treating physician will be aware of all medications that a patient may be taking, that informs the treating physician of possible drug interactions or drug dosage and administering duration that are outside of recommended ranges, that permits contacting the patient when his medication is due regardless of where the patient may be located at that moment, that assists the treating physician in prescribing not only the best medication, but also a dosage and duration that is within recommended ranges, as well as a system that streamlines the number of medications that the patient is taking, and that incorporates automatic mail ordering, billing, and other business aspects of prescribing a medical regimen.

OBJECTS AND SUMMARY OF THE INVENTION

Therefore, one object of this invention is to provide a system which better addresses the causes contributing to the inaccurate use of prescription drugs and reducing noncompliance by a patient of the medical regimen prescribed for the patient.

Another object of this invention is to provide a system that identifies for the treating physician possible dosing, administering duration, or drug interaction problems that might result from a prescribed medication regimen.

Another object of this invention is to provide a system that has the ability to assist the treating physician in prescribing the best medical regimen for the patient and not merely the most convenient.

A further object of this invention is to provide a system that enables the treating physician to streamline the number of medications in a medical regimen, as well as to reduce polypharmacy problems.

Still another object of this invention is to provide a system that has the ability to contact patients no matter where they may be located at a particular time.

A still further object of this invention is to provide a system that has the ability to contact patients when their medication is due and not after the fact.

Another further object of this invention is to provide a system that has the ability to timely remind patients to refill prescriptions.

Another object of this invention is to provide a system that assists in the ordering of prescription refills in a manner that reduces costs to the entity paying for the prescriptions.

A still further object of this invention is to provide a system that can generate reports useful to the treating physician, the patient, the medication provider, and the medication regimen payment source.

Another object of this invention is to provide a system that assists in improving the communication between the treating physician and the patient, in notifying the patient of upcoming appointments, and in specifying procedures in the medical regimen that the patient should follow.

Other objects and advantages of the invention will become apparent from the ensuing descriptions of the invention.

Accordingly, a system to facilitate compliance with a prescribed medical regimen is provided, which comprises a computer system having a data storage unit containing stored pharmaceutical data, a central processing unit (CPU) programmed and operatively connected to the data storage unit to further store in the data storage unit patient data and patient prescription data, and an inputting unit operatively connected to the CPU to transmit patient data and patient

prescription data to the CPU, and a reporting unit operatively connected to the CPU; the CPU being further programmed to compare the patient data, the patient prescription data, and the pharmaceutical data to determine if the patient prescription data is within an acceptable medication dosage range as defined by the pharmaceutical data, and to transmit the determination to the reporting unit.

In a preferred embodiment of the invention, the CPU is further programmed to compare the patient data, the patient prescription data and the pharmaceutical data to determine if the patient prescription data is within an acceptable medication administering duration range as defined by the pharmaceutical data, and to transmit the determination to the reporting unit.

In another preferred embodiment of the invention, the CPU is further programmed to compare the patient data, the patient prescription data and the pharmaceutical data to determine if the patient prescription data is within an acceptable medication maintenance dosage or within an acceptable medication acute dosage range as defined by the pharmaceutical data, and to transmit the determination to the reporting unit.

In still another preferred embodiment of the invention, the CPU is further programmed to generate from approved patient prescription data a patient message, and wherein the system further comprises a message receiving unit operatively connected to the CPU to receive the patient message from the CPU. In a more preferred embodiment, the message receiving unit will comprise a modem operatively connected to a transmission unit which can transmit the patient message to a pager. Alternatively, there may be embodiments wherein the CPU and the transmission unit are directly connected and do not need a message receiving unit (e.g. modem) to accomplish communications between the CPU and transmission unit.

In still another preferred embodiment of the invention, the CPU is further programmed to generate a prescription delivery message, and wherein the system further comprises a message receiving unit operatively connected to the CPU to receive the prescription delivery message from the CPU.

In a further preferred embodiment of the invention, the system comprises two or more linked computer systems. One computer system is the server computer station and the other computer systems are prescriber computer systems. The server computer station will serve as the repository of the data bases used by each of the prescriber computer systems and will deliver that portion of the data bases requested by one of the prescriber computer stations. Each prescriber computer station shall then process the information provided by the server computer station, as well as information which it may have stored in its own data base storage unit, in accordance with instructions set forth in its operating program. The prescriber computer station will be further provided with one or more communication units, such as a modem, for transmitting messages, including prescription orders, determined by the results of the processed information to the server computer station. The server computer station upon receipt of these messages, and in accordance with its operating program, will timely transmit these messages to pre-determined parties.

BRIEF DESCRIPTION OF THE DRAWINGS

The specification and the accompanying drawings show and describe a preferred embodiment of this invention, but it is to be understood that this embodiment is not intended to be exhaustive nor limiting of the invention, but on the contrary is given for the purpose of illustration in order that others skilled in the art may fully understand the invention and the principles thereof and the manner of applying it in practical use so that they may modify and adapt it in various forms, each as may be best suited to the conditions of a particular use.

FIG. **1** is schematic of an overview of a preferred embodiment of the system of this invention.

FIG. **2** is a schematic of a preferred embodiment of the system that illustrates the flow of data, reports, and verbal communication within the system and method of use of the system.

FIG. **3** is a schematic of a preferred embodiment of the computer software architecture utilized by the system and the method of use of the system detailing the steps taken by the physician and the reports generated by the system.

FIG. **3A** is a schematic of a preferred embodiment of the computer software architecture utilized by the system to check the drug dosing for over dose, under dose, and length of therapy.

FIG. **3A-1** is a schematic of a preferred embodiment of the subroutine of the computer software architecture utilized by the system to determine if the prescribed drug regimen is within the recommended daily and unit drug dosage ranges.

FIG. **3A-2** is a schematic of a preferred embodiment of the subroutine of the computer software architecture utilized by the system to determine if the prescribed drug regimen is within the recommended drug duration range.

FIG. **3B** is a schematic of a preferred embodiment of the computer software architecture utilized by the system to check for adverse drug interactions among the drugs included in the patient medical regimen.

FIG. **4** is a schematic of a preferred embodiment of the computer software architecture utilized by the server system to forward to the patient messages relating to the patient's medical regimen.

PREFERRED EMBODIMENTS OF THE INVENTION

Although it is within the scope of this invention that each prescriber could be equipped with a computer system that would perform all of the functions discussed below, the preferred system includes a central server computer system A to which will be operatively connected to one or more prescriber computer systems B. In this preferred embodiment the central processing units (CPUs) of each computer system will be programmed to perform separate tasks. In the stand alone system, the CPU of the prescriber will be programmed to perform all of the separate tasks. It is also within the scope of this invention that the tasks to be performed could be achieved by either the server CPU or the prescriber CPU through well known and easy to perform programming changes. It is also within the scope of this invention that the retention of the various types of data maintained by the system could be retained either in the internal hard drives of the server computer system A or the prescriber computer system B, or in external memory units operatively attached to either, or through the use of other known data storage media.

The Computer Hardware Utilized in the Preferred System

It is seen from FIG. **1** that in the preferred embodiment of the invention, the system comprises a server computer station A, and a prescriber computer station B which are

programmed to provide drug dosage, administering duration, drug interaction and patient drug reaction checks from the data stored in the two stations. In a more preferred embodiment, the system will also comprise a patient message receiving system C through which the patient can be timely reminded to take the medication contained in the medical regimen. In another more preferred embodiment, the system will also comprise a prescription distribution system D that enables quicker initial delivery and which better ensures timely refills of prescriptions. In still another more preferred embodiment, the system may also comprise an invoice payment system E that expedites payment, and reduces payment processing costs. With the equipment contained in each system, each of the communications graphically depicted in FIG. 2, and discussed below, is made possible.

In the most preferred embodiment, the server computer station A comprises a central processing unit (CPU) 1; a data storage unit, such as a disc and/or hard drive 2, for storing patient data, patient prescription data, pharmaceutical data and the CPU's operating programs; a data input unit, such as a keyboard 3, for inputting data or operating instructions into CPU 1; one or more communication units, such as modems 4 and 5, for transmitting data or messages to the prescriber computer station B or the patient message receiving system C; and a printer 6 for preparing hard copies of invoices or reports generated by the server CPU 1 or the prescriber computer station B. Each of the elements making up the server computer station A are operatively connected to one another by well known means, such as hard wiring, telephone lines, microwave transmission means, and similar devices, to permit the functions which each element normally performs. Additionally, where this specification discusses communication through modems, the manner of communication is not necessarily limited to modems. Where feasible, certain modem communications described herein could be accomplished through network connections or various wireless communications.

The prescriber computer station B comprises a central processing unit (CPU) 7; a data storage unit, such as a CD and/or hard drive 8, for storing patient and patient medical regimen data, and the CPU's operating programs; a data input unit, such as keyboard 9, for inputting data or operating instructions into CPU 7; an audio speaker or video monitor 10; a printer 11; and a communication unit, such as modem 12, for transmitting data to and receiving data from the server computer station A. Similar to server computer station A, each of the elements making up the prescriber computer station B are also operatively connected to one another by well known means to permit the functions which each element normally performs.

In a preferred embodiment, the patient message unit C comprises a message receiving and sending means 13 and a pager 14, and more preferably a two-way pager. Means 13 will include a modem 15 and a pager transmitting unit 16. In a more preferred embodiment pager 14 is a two-way pager to permit the patient to confirm receipt of the message, as well as respond to any queries contained in the message. Such inquiries may include questions related to the health of the patient. The term "pager" as used throughout this specification is intended to include within its definition any addressable communication device which is capable of receiving a message. Such an addressable communication device could be capable of providing one-way or two-way communication. Preferably, the addressable communication device will be portable. Thus, a pager could include a cellar or digital wireless telephone and in particular a wireless telephone which incorporates a digital paging function. A pager could also include a miniature portable computer such as "palm" computers which allow wireless communication with the Internet. Therefore, a page be in the form of a conventional E-mail message and a pager be any device capable of receiving the E-mail message. One such palm computer is the PALM III™ manufactured by 3Com Corporation of Santa Clara, Calif. The preceding description of pager embodiments is intended to be illustrative only and those skilled in the art will recognize many other existing or future addressable communication devices could come within the definition of pager.

In a preferred embodiment, the prescription distribution system D includes a modem 17 and a CPU 18 for receiving the information and transcribing this information in a format that enables one to prepare the medication prescribed by the physician. In a more preferred embodiment, the prescription distribution system D will also comprise a reporting unit, such as printer 19 and CRT monitor 20, which permits viewing of the billing statement and subsequent printing of a hard copy of the billing statement that is to be transmitted to the payor of the medication delivered to the patient. The payor may be the patient, a healthcare payor, or government agency.

In a preferred embodiment, the invoice payment system E will include a computer system, including modem 21 operatively connected to the prescription distribution system D to receive a billing statement for the medication prescribed, a CPU 22 to process the information contained in the billing statement, as well as a CRT monitor 23 and printer 24 to view and print checks, as well as other information. As reflected in FIGS. 1 and 2, this information can utilize the server system A as a conduit for transmitting the billing statement. If server system A is provided with a data base containing the payor identification and drug cost charged by the prescription delivery service D, then server system A can directly generate and transmit the billing statement to the payment system E.

Alternatively, the prescription delivery system D and the payor system E could be directly linked by computers to transmit the billing statement and to make payments directly to the prescription delivery system D.

It is within the scope of this invention that for each of the computer elements used in the server computer station A, the prescriber computer station B, the patient message unit C, the prescription distribution system D, or the payment system E, devices which perform the same function, or which perform one or more of the functions described, could be substituted for the preferred computer element, or elements. As an example, a voice recognition system could be substituted for the keyboards 3 or 9. Another example would include the substitution of a speaker system for the monitors 10, 20, or 23. A still further example would include the use of separate database storage units such as tape systems for the hard drives 2 or 8. The particular computer hardware that is used is not critical. It is important, however, that there be a computer element present to perform the desired function. The term "computer" is intended to include all existing and future computing devices. By way of example, present computers include palm top computers or personal digital assistants (PDA's). It should also be understood that communications between various components of the system need not be direct or through dedicated lines, but could be via the Internet.

The Communications Amongst Users of the System

FIG. 2 illustrates an overview of a preferred use of the server computer station A to obtain a preferred flow of data,

reports, and messages amongst the physician, the prescription distribution service organization, the patient, and the prescription payor. The various channels of information flow are described below as indicated by the information flow numbers in FIG. 2.

1. The prescriber utilizing the prescriber computer station B enters information about the patient that is then transmitted to the server computer station A. If the patient is currently being prescribed by another prescriber in the system, or has been prescribed in the past by a prescriber in the system, the patient's billing, medical, and prescription history will already exist within the server data base Unit 2. This information will be communicated to the prescriber computer station B.

2. The patient is assigned a pager **14**. If the patient already has pager **14** the assignment is not necessary.

3. Prescription information for the patient is entered into the system by the prescriber. This information includes, but is not limited to, drug name, units and strength, prescription signature, refills, dosing mode, and a date and time that the first dose is to be administered. Pharmaceutical information related to the drugs being prescribed is transmitted from the server computer station A to the prescriber computer system B. There the pharmaceutical information is compared to the patient data and patient prescription data to ascertain if the drug regimen is within recommended ranges and to determine if any drug interaction problems exist. These include a series of tests performed on the prescription to see if it may have adverse effects. These tests include, but are not limited to underdosing, overdosing, length of therapy, drug-drug interactions, drug-food interactions, drug-alcohol interactions, and prior adverse reactions. Any of these circumstances will be reported to the person, such as the treating physician, entering the prescription information, where an appropriate action can be taken.

4. Once the drug regimen has been finalized, the prescription data is transferred to the server for validation, certification, and distribution.

5. Messages are scheduled for distribution to the patient via the patient message receiving system C. This schedule can easily be changed by the prescriber through the system.

6. Prescriptions can be distributed to a prescription distribution company, such as a pharmacy, or drug wholesale company, and in turn the distribution company can, via the server, invoice the payor (see 11 below).

7. Patient reporting may be provided, including but not limited to, general information, prescription history, and prescription calendar. This reporting would be made to the prescriber via the server, or could be made directly to the prescriber.

8. Responses to the messages are received from the patient and recorded for reporting to the prescriber.

9. Compliance information is reported to the prescriber. This type of reporting is available only if the patient message receiving system C is capable of providing an answer back capability, such as may be provided by a two-way pager.

10. Changes to the prescription including drug, time and date of treatments, etc. are communicated to the prescriber. All changes are initiated by the prescriber, who can make the changes via the steps described above.

11. Billing and other communications can be made with the prescription payor.

The Method of Utilizing the System for Medical Regimen Integrity

FIGS. 3 and 4 illustrate a preferred scheme using the prescriber computer system B and the server computer system A, respectively, to perform each of the steps involved in developing and monitoring a prescribed drug regimen. FIGS. 3A and 3B are preferred software subroutines used in the prescriber computer system B to check whether the prescribed drug is within the recommended dosage range and whether the prescribed drug creates any objectionable interaction with other drugs which the patient is taking, respectively. FIG. 3A-1 is a more preferred software subroutine within the dosage range check routine to determine if the prescribed drug regimen is within the recommended daily dosage range and within the recommended unit dosage. FIG. 3A-2 is a more preferred software subroutine to determine if in the standard medication mode, the total dosage is within the recommended duration range.

1. Inputting the pharmaceutical data As one of the initial steps in preparing the system for use, pharmaceutical data will be inputted and stored in the server data storage unit 2. For each drug in the pharmaceutical data base, this data will include the prescription identification code (which will be found in the GPI or NDC identification codes), the GPI, the NDC and the KDC, the class of chemical components of the prescribed drug, the recommended unit dosage, the recommended standard daily dosage range, the recommended acute dosage range including the unit, daily, and prescribing duration acute ranges, the recommended maintenance unit, daily, and duration dosage range, and the recommended route, or routes, in which the drug is to be administered. This data is provided by the various pharmaceutical companies to the U.S. FDA which accumulates and distributes the information. While this specification generally discusses prescription drugs, it should be understood that the scope of the present invention includes both nonprescription "over-the-counter" medications and nontraditional medications. Examples of nonprescription medications include aspirin, Tylenol, common cold remedies, etc. Examples of nontraditional medications could include herbal substances, vitamins, or various holistic medical preparations.

2. Inputting the patient and patient prescription data The prescriber will in most cases, but not necessarily in all cases, be the patient's treating physician who desires to prescribe a particular medication to the patient to assist in the treatment of some medical illness. The prescriber computer station 7 is constructed to permit the prescriber to input into the system that patient data and patient prescription data necessary for the prescriber to ascertain that the dosage of the prescribed medication is within the recommended standard unit dosage, daily dosage or duration ranges, acute unit and daily dosage ranges, as well as the acute duration range; maintenance unit and daily dosage ranges, as well as the maintenance duration range, or if there is likely to be a drug-drug interaction, a drug-food interaction, a drug-alcohol interaction; or if there has been a prior adverse reaction by the patient to the particular drug or class of drugs being prescribed.

The patient prescription data will include the patient's identification code (e.g., social security number), the prescription GPI or NDC, the prescribed unit dosage, the prescribed daily dosage, the number of refills, the schedule of taking the prescribed drug, including time of first administration and frequency of administration, and the administering mode (i.e., standard, acute or maintenance mode). The patient prescription data will also include similar information for any other drug which the patient is currently taking. The patient prescription data can also include for each drug in the medical regimen the prescriber's name, the prescriber's practice name, address, and telephone number.

In a more preferred embodiment of the invention, it will also permit the inputting of patient data that will include the

information necessary to expedite the delivery of the prescribed medication to the patient, to expedite the payment process for the prescribed medication, to generate patient messages to prompt the timely taking of the prescribed medication; and to continue to monitor the taking of the prescribed medication.

This patient data would include the patient's name, social security number, and address. It can also include the identification code of the pager assigned to the patient, as well as the name, address, telephone number, facsimile number, or identification number of the prescription delivery service D to be used to prepare and deliver the prescription. It can also include similar information regarding the entity, if other than the patient, who will pay part or all of the cost of the prescription. The patient data may also include medical history information relating to the patient, such as prior adverse reactions to specified drugs. It may also include such other information as patient height and weight, or any other general health information which the prescriber may believe beneficial in establishing a medical regimen for the patient.

Turning now to FIG. 3, in step **100**, the prescriber logs into the software program and enters the patient's identification code. The preferred identification code will be the patient's social security number. The software will automatically connect the prescriber CPU **7** to the server CPU **1** through the use of modem **12** and modem **4**. The server CPU **1** will search the patient data contained in the server data storage unit **2** to determine if previous patient data or patient prescription data had been entered regarding the particular patient in question. If so, ibis information is then transmitted to the prescriber CPU **7**. If not, then in step **101** the prescriber will input through keyboard **9** the necessary patient and patient prescription data. The prescriber CPU **7** is further programmed to display the patient data on monitor **10** or, at prescriber's option, to print a hard copy of the patient data by use of printer **11**. There is no preferred software to accomplish the above tasks. Any of the many commercially available data base and communication software programs can be used. While FIG. **3** describes the prescriber CPU **7** as having a program to carry out the functions described in FIG. **3**, it will be clear to those skilled in the art that such functionality could be achieved without the program being in the memory of the computer housing prescriber CPU **7**. Rather, one alternative would be to have the functionality of the prescriber program incorporated into a website. In this manner, the prescriber would not need specialized software, but only need sufficient conventional hardware and software so as to be web capable.

3. Assignment of Pager. As indicated above, one of the preferred embodiments of this invention is a reminder system which provides prior notification to the patient that certain of his prescribed medications should be administered. One of the problems with prior art systems is that patients are mobile. As a result many of the reminder messages are not timely received by the patient. Therefore, the preferred mode of communicating with the patient is by pager **14**.

In a more preferred embodiment, the pager **14** will be a two-way pager which permits the patient to indicate receipt of the message. This system also permits the message to include not only a reminder to take the prescribed medication, but also to query the patient on other health matters, and to receive from the patient an updated status as to the health of the patient, the effectiveness of the prescribed medical regimen, or any health problems that may have arisen as a result of the prescribed medical regimen.

To effect this preferred mode, in step **200** the software program is structured to search the patient data located in the server storage unit **2** and the prescriber storage unit **8** to determine if a pager had been previously assigned to the patient. If no pager has been previously assigned to the patient, then in step **201** a pager is assigned by inputting the pager identification code into the patient data. This information is transmitted to the server computer system A which will in step **202** transmit a test message in accordance with the procedure described in FIG. **4** and discussed below.

4. Entering the patient prescription data. Upon verification that a pager has been assigned to the patient, the prescriber then inputs in step **300** through keyboard **9** that portion of the patient prescription data identified above that is necessary to verify that the prescription complies with a recommended dosage range, a recommended administering duration range, is free of adverse drug-drug reactions, drug-food reactions, drug-alcohol reactions, and known prior patient adverse drug reactions.

From this patient prescription data and the patient data, the prescriber CPU **7** is in step **400** programmed to generate a drug regimen that is then transmitted through modems **12** and **4** to the server CPU **1** for retention in the server data storage unit **2**.

In a preferred embodiment, the prescriber will indicate if information identifying the drug being prescribed is to be made available to other prescribers. This embodiment permits the prescriber to maintain certain information confidential and be disseminated on a need-to-know basis. This is achieved by designating at step **500** the drug description as confidential. Although a drug has been designated as confidential, the system is preferably designed to still perform the dosage range check, the drug interaction checks, and the prior patient adverse drug reactions check. Thus, another prescriber will know if the unidentified drug causes any problem with a drug which the prescriber may wish to administer. In this circumstance, a message providing the prescriber's name and telephone number will be entered into the patient data. When the patient data is subsequently recalled, another prescriber will thus have the ability to contact the originating prescriber and determine the identity of the prescription.

In another preferred embodiment, the prescriber can indicate if the drug being prescribed is an experimental drug. This is also achieved in step **500** by designating the drug as experimental. Howevér, in this event there is no further drug dosage check or drug interaction check, as there will not be sufficient information in the data bases to make those determinations.

5. Prescribed Dosage Check Procedure. Upon the transmittal of the drug regimen to the server data storage unit **2**, the prescriber CPU **7** is programmed in step **600** to request that the server CPU **1** retrieve from the server data storage unit **2** the pharmaceutical data relating to each of the prescriptions contained in the schedule, as well as to each of the other prescriptions which the patient is currently taking. With this information, and as further described in FIG. **3A**, the prescriber CPU **7** is programmed to check each prescription to determine if it is within the recommended unit dosage range or the recommended daily dosage range, as well as within the recommended medicating duration range for the prescribing mode; i.e., standard, acute, or maintenance. In a preferred embodiment, the program is constructed to default to a standard dosage mode. However, if the prescriber had indicated that the drug regimen has been set for a maintenance or acute dosage, then as detailed below in FIG. **3A**, each such prescription is checked to determine if it is within the recommended maintenance dosage ranges or the recommended acute dosage range, whichever may be indicated.

If the prescription is not within the recommended ranges, then the prescriber CPU **7** is programmed to display this information on the prescriber monitor **10** where the prescriber is directed to amend the prescription to be within the recommended ranges.

(a) Dosage and Duration Range Check

FIGS. **3A**, **3A-1**, and **3A-2** provide a preferred software routine for the method of conducting a comparison of the patient data and the patient prescription data to the associated pharmaceutical data to determine if there are any deviations from recommended dosage or duration ranges.

In addition, the prescriber CPU **7** has been programmed to transmit its determinations to prescriber monitor **10** and printer **11**. Also, along with the determinations, suggested actions may be provided to the prescriber. Although the language used, as well as the content of the determinations and suggested actions may vary within the scope of the invention, the following would be exemplary of the messages provided to the prescriber or physician:

MESSAGE NUMBER	MESSAGE DESCRIPTION
1	Adult Dose Checking is not Available.
2	Geriatric Dose range checking is not available. Comparison to normal adult dosing may or may not be appropriate.
3	Pediatric Dose Range Checking is not available. Consult a pediatric dosing reference is recommended.
4	Infant Dose Checking is not available. Consult a pediatric dosing reference is recommended.
5	This dose falls below the recommended daily dose for this drug and is potentially subtherapeutic.
6	This dose falls above the recommended daily dose for this drug. Please verify this daily dose.
7	This dose falls above the recommended maximum individual dose for this drug. Please verify the dosage regimen.
8	No further information available.
9	This dose falls below the recommended maintenance dosage range for this drug and is potentially subtherapeutic.
10	This dose falls above the recommended maintenance dosage range for this drug. Please verify this daily dose.
11	This dose falls below the recommended acute dosage range for this drug and is potentially subtherapeutic.
12	This dose falls above the recommended acute dosage range for this drug. Please verify this daily dose.
13	The duration of therapy falls below the recommended duration of therapy range for acute dosing and is potentially ineffective.
14	The duration of therapy exceeds the recommended duration of therapy range for acute dosing of this drug. Please verify the prescribed length of acute therapy.
15	Minimum Duration of Therapy is not available.
16	Maximum Duration of Therapy is not available.
17	The duration of therapy falls below the recommended duration of therapy range and is potentially ineffective.
18	The duration of therapy exceeds the recommended duration of therapy range for this drug. Please verify the prescribed length of therapy for this drug.

When these messages are preferably transmitted is set forth below.

The first step **601** is to calculate the age of the patient from the information in the patient data. If this information is not in existing patient data, then the prescriber will input in the necessary information to calculate the age of the patient.

Recommended dosage ranges may vary depending on the age of the patient. Currently, dosage ranges have been defined for infants (ages of 0–1), adolescents (ages of 1–14), adults (ages 14–65) and geriatrics (ages >65). This age division is used by the system to provide dosage range checks. Obviously, if these current divisions change, then the software program could be easily modified to accommodate such changes.

Next, in step **602**, the prescriber central processing unit **7** is programmed to determine if the patient age is **65** or greater. Then the GPI or NDC is read at step **603**. If the GPI or NDC is not stored in the server data storage unit **2**, prescriber central processing unit **7** will perform step **604** to transmit to prescriber report unit **10** a message that geriatric dose range checking is not available. The message may also provide guidance to the prescriber, such as comparison to normal adult dosing may or may not be appropriate (Message Number 2). The prescriber CPU **7** is then further programmed to begin at step **612**, described below, to check to determine if there is a prescription identification number included within the adult dosage category. If the GPI or NDC is stored in the server data storage unit **2**, then the prescribed dosage and the recommended adult dosage range are compared in step **605** to determine if the prescribed dosage is within the recommended adult dosage range.

(i) Dosage Range Check. Step **605** is set forth in more detail in FIG. **3A-1**. In the first step **605A** the prescriber CPU **7** is programmed to calculate a DoseUnit (daily dosage). This is obtained by dividing the total drug quantity by the prescribed duration. In step **605B** the prescriber CPU **7** is programmed to calculate an IndividualDose (unit dosage). This is obtained by dividing the DoseUnit by the frequency a patient is to take the medication. Next, in step **605C** a comparison is made by the prescriber CPU **7** between the prescribed daily dosage and the recommended minimum daily dosage. If the prescribed daily dosage is less than the minimum recommended daily dosage, prescriber CPU **7** is programmed in step **605D** to generate a message for transmission to the prescriber monitor **10** and then proceed to step

605E. The message would indicate that the prescribed daily dosage is less than any dosage in the recommended total daily dosage range and that the prescribed dosage is potentially subtherapeutic (see Message Number 5). However, if the prescribed daily dosage is greater than the recommended minimum daily dosage, the prescriber CPU 7 is programmed in step 605E to compare the prescribed daily dosage to the recommended maximum daily dosage. If the prescribed daily dosage is greater than the recommended maximum daily dosage, then the prescriber CPU 7 is programmed in step 605F to generate a message for transmission to the prescriber monitor 10 and then proceed to step 605G. The message would indicate that the prescribed dosage falls above the recommended daily dose for the drug, and requests the prescriber to verify the prescribed daily dose (See Message Number 6). If the prescribed daily dosage is less than the maximum daily recommended dosage, then the prescriber CPU 7 in step 605G compares the prescribed unit dosage to the recommended maximum unit dosage. If the prescribed individual dosage is greater than the recommended maximum unit dosage, prescriber CPU 7 is programmed in step 605H to generate a message for transmission to prescriber monitor 10 that the prescribed dosage falls above the recommended unit dosage for the drug, and requests the prescriber to verify the prescribed dosage regimen (See Message Number 7) and to proceed to the maintenance mode range check at step 615. If the prescribed unit dosage is below the recommended unit dosage, then prescriber CPU 7 is programmed as described below to determine if the prescribed dosage is within the mode ranges being prescribed.

Returning now to FIG. 3A, if the age of the patient is less than 65, but determined in step 606 to be less than 14 years, then, in step 607, it is determined if the age of the patient is greater than one year. If not, then, in step 608, prescriber CPU 7 is programmed to generate a message that infant dose checking is not available. It may also recommend that the prescriber consult a pediatric dosing reference (See Message Number 4). Once the message has been transmitted, the prescriber CPU 7 is programmed to terminate the dosage check subroutine and proceed to the drug interaction check subroutine. If the age of the patient is determined to be between 14 years and one year, then, in step 609, the GPI or NDC is read from the prescription data. If, in step 610, no matching GPI or NDC can be located in server data storage unit 2, then prescriber CPU 7 is programmed in step 611 to generate a message that pediatric dose range checking is not available. The message may recommend that the prescriber consult a pediatric dosing reference (See Message Number 3). Once the message has been transmitted, the prescriber CPU 7 is programmed to terminate the dosage check subroutine and to proceed to the drug interaction check subroutine. However, if a GPI or KDC is located in step 610, then prescriber CPU 7 is programmed to perform step 605 previously described.

If, in step 606, the age of the patient is determined to be between 15 years and 65, then, in step 612, the GPI in the prescription data is read by the prescriber CPU 7 and compared in step 613 to the GPI's stored in server data storage unit 2 to determine if pharmaceutical data is stored in the server data storage unit 2 corresponding to the GPI. If not, then, in step 614, prescriber CPU 7 is programmed to generate a message that adult dosage checking is not available (See Message Number 1). After the message has been transmitted, prescriber CPU 7 is programmed to end the dosage range check and to begin the drug interaction check subroutine at step 700. If the pharmaceutical data corresponding to the GPI is located in the server data storage unit 2, in step 613, the prescriber CPU 7 is programmed to begin Dose Range Check step 605. In a preferred embodiment the DNC will contain a corresponding GPI designation for each drug in the DNC. Thus, if the prescriber inputs DNC designations into the prescriber CPU 7, the software is designed to located the corresponding GPI designation and then to utilize the GPI designation to obtain the necessary data to perform the checks.

In step 615, prescriber CPU 7 is programmed to determine if the patient prescription data indicates that the prescription dosage is a maintenance dosage. If so, then prescriber CPU 7 is programmed to determine if the prescription dosage is within associated recommended maintenance dosage ranges. In step 616, it is determined if the prescription dosage is greater than the maximum maintenance dosage in the recommended maintenance dosage range. If not, then, in step 617, it is determined if the prescription dosage is less than the minimum maintenance dosage in the recommended maintenance dosage range. If it is, then, in step 618, the prescriber CPU 7 is programmed to generate a message that the dosage falls below the recommended maintenance dosage range for this drug and is potentially subtherapeutic. (See Message Number 9) If in step 617 the prescribed dosage is greater than the recommended minimum maintenance dosage, then the prescriber CPU 7 is programmed to conclude the dosage check subroutine and to proceed with the drug interaction check subroutine.

If in step 616 the prescribed dosage is greater than the recommended maximum maintenance dosage, then in step 619 the prescriber CPU 7 is programmed to search to determine if an acute dosage record exists. If no record can be found, then in step 620 the prescriber CPU 7 is programmed to generate and transmit to prescriber monitor 10 a message that the prescribed dosage falls above the recommended maintenance dosage range for the drug, and requests the prescriber to verify the daily prescribed dosage. (See Message Number 10) Upon transmission of the message, the prescriber CPU 7 is programmed to terminate the dosage check subroutine and to proceed with the drug interaction check subroutine.

If the prescription data indicates that the dosage prescribed is an acute dosage, then in step 621, the prescribed dosage is checked to determine if it is within the recommended acute dosage range associated with that prescription. If the prescribed dosage exceeded the maximum acute dosage range, then, in step 622, the prescriber CPU 7 is programmed to generate a message that the dose falls above the recommended maximum acute dosage for this drug. The message can include suggestions to the prescriber such as requesting the prescriber to verify the daily dosage. (See Message Number 12) Upon transmission of the message, the prescriber CPU 7 is programmed to begin the drug interaction check subroutine. If the prescribed dosage is not greater than the maximum acute dosage in the recommended acute dosage range, then, in step 623, it is determined if the prescribed dosage is less than the minimum acute dosage in the recommended acute dosage range. If it is, then, in step 624, the prescriber CPU 7 is programmed to generate a message that the prescription dosage falls below the recommended acute dosage range for this medication and is potentially subtherapeutic. (See Message Number 11) Upon transmission of the message, the prescriber CPU 7 is programmed to begin the drug interaction check subroutine. However, if the prescription dosage is not less than the minimum acute dosage in the recommended acute dosage range, then, in step 625 the prescriber CPU 7 is programmed

to calculate the prescribing duration for the drug being checked. The prescribing duration is determined by dividing the total quantity prescribed by the daily quantity prescribed. Then with the calculated prescribing duration, prescriber CPU **7** is programmed to determine in step **626** if the prescribing duration period is greater than the maximum acute duration period in the recommended acute duration period range. If the prescribing duration period is greater, then, in step **627**, the prescriber CPU **7** is programmed to generate a message that the duration of therapy exceeds the recommended duration of therapy range for acute dosing of this drug. It may also suggest that the prescriber verify the prescribed length of acute therapy. (See Message Number 14) If the prescription duration period is less than the maximum duration period in the recommended duration period range, then, in step **628**, it is determined if the prescription duration period is less than the minimum duration period in the recommended duration period range. If not, then the prescriber CPU **7** is programmed to terminate the drug dosage check and to proceed to the drug interaction check subroutine. However, if the prescription duration period is less than the minimum recommended duration period, then, in step **629**, prescriber CPU **7** is programmed to generate a message that the duration of therapy falls below the recommended duration of therapy range for acute dosing and is potentially ineffective. (See Message Number 13) Upon transmission of the message, the prescriber CPU **7** is programmed to begin the drug interaction subroutine.

If the prescription is not a maintenance mode dosage or if no maintenance record can be located in step **615**, then prescriber CPU **7** is programmed to determine in step **630** whether an acute mode record exists. If an acute mode record exists, then prescriber CPU **7** is programmed to begin step **621** as described above. If no acute mode record exists, then prescriber CPU **7** is programmed to begin in step **631** the drug prescribing duration check subroutine.

(ii) Prescribing Duration Check Referring now to FIG. 3A-2, prescriber CPU **7** is programmed to calculate the prescribing duration for each new drug to be prescribed in a medical regimen. This step **631**A is substantially the same as step **625**. Prescriber CPU **7** is then programmed to search in step **631**B the pharmaceutical data to determine if there is a recommended minimum prescribing duration period for the drug being checked. If none is found, then prescriber CPU **7** is programmed to generate and transmit to monitor **10** in step **631**C a message, and then to proceed to step **631** D. The message would indicate that there is no recommended minimum prescribing duration (See Message Number 15).

Prescriber CPU **7** is programmed to then search the pharmaceutical data to determine in step **631**D if there is a recommended maximum prescribing duration. If none is found, the prescriber CPU **7** is programmed to generate and transmit to monitor **10** in step **631**E a message, and then proceed to step **631**F. The message would indicate that there is not a recommended maximum prescribing duration (See Message Number 16).

If a recommended minimum prescribing duration was found in step **631**F, then prescriber CPU **7** is programmed to determine in step **631**F if the calculated prescribing duration is less than the recommended minimum. If so, then prescriber CPU **7** is programmed to generate and transmit to monitor **10** in step 631G a message to this effect (See Message Number 17). The prescriber CPU **7** is also programmed after sending the message to proceed to step **631**H. Similarly, in steps **631**H and **631**I, prescriber CPU **7** is programmed to determine if the calculated prescribing duration is greater than the recommended prescribing duration for the drug being checked. If so, a message to this effect (See Message Number 18) is generated and transmitted to Monitor **10**.

6. Drug Interaction Checking Procedure. Prescriber CPU **7** is next programmed in step **700**, as referenced in FIG. 3 and 3B, to retrieve from the previously transmitted pharmaceutical data now stored in the server data storage unit **2** the information necessary to determine if any of the drugs included within the medical regimen will cause an unacceptable reaction with any other drug included within the medical regimen. The preferred subroutine is illustrated in FIG. 3B.

In step **701**, the prescriber CPU **7** is programmed to create an empty interaction list. Next, in step **702**, the prescriber CPU **7** is programmed to compare the GPI of a prescribed drug with the NDC stored in the server data storage unit **2** in order to collate the GPI with the corresponding NDC to locate the KDC. If in step **703**, the corresponding KDC is located, then in step **704** the KDC is retained by the prescriber CPU **7**. The prescriber CPU **7** is programmed in step **705** to include the finding in a final report. If the KDC in step **703** was not found, then the prescriber CPU **7** is programmed to retain that finding. In the next step **707**, prescriber CPU **7** searches the pharmaceutical data to look for the drug formulation record (containing the compound classes which the drug contains) for each drug in the medical regimen. If at step **708** the record is found, then prescriber CPU **7** is programmed at step **709** to create a list of classes that each drug in the medical regimen would be classified, and at step **710** to retain the finding. If at step **708** no drug formulation record could be found, then prescriber CPU **7** is programmed to retain at step **711** this finding. The prescriber CPU **7** is programmed to compare the classes of each drug in the medical regimen to determine at step **712** if there would be any anticipated unacceptable drug interactions because of the compound classes in which a drug may be included. Any unacceptable drug interactions located are accumulated in a list at step **713**. If there are unacceptable drug interactions included in the list, then the prescriber CPU **7** is programmed to generate and then instruct prescriber printer **11** in step **714** to print the findings of the drug interaction test or display on monitor **10** these findings. The prescriber may then modify the drugs being prescribed to eliminate the unacceptable drug interactions. If there are no unacceptable drug interactions, the prescriber CPU **7** is programmed to end the drug interaction check subroutine and to proceed to step **800** to check for prior patient reactions to any drug being prescribed in the medical regimen.

If there are unacceptable reactions between drugs included within the medical regimen, the prescriber CPU **7** is programmed to display this information on the prescriber monitor **10**. The prescriber then modifies one or more of the drugs to eliminate the unacceptable reaction. The new prescriptions are then checked for compliance with both the dosage and duration ranges, as well as for unacceptable drug interactions. This procedure is repeated until the prescribed medical regimen meets the recommended standards.

7. Prior Drug Reaction Checking Procedure. Once the prescribed medical regimen is within the recommended dosage and duration ranges and there are no unacceptable drug interactions, the prescriber CPU **7** is programmed in step **800** to search the patient data to determine if the patient has ever reported any adverse reaction to any of the drugs, or classes of drugs, in the prescribed medical regimen.

If so, the prescriber CPU **7** is programmed to display this information on the prescriber monitor **10**. The prescriber

then modifies the prescribed medical regimen to eliminate the unacceptable known reaction. The modified regimen is then again checked for dosage, administering duration, drug interaction, and prior known drug reactions. The procedure is repeated until the prescribed medical regimen meets all of the recommended dosage and duration range requirements, and there is no unacceptable drug interaction and drug reactions.

8. Report Generation Procedure. Once the medical regimen has been set, the prescriber CPU **7** is programmed in step **900** to direct prescriber printer **11** to print for the patient, the prescription calendar and prescribed medical regimen for the patient to follow. The prescriber CPU **7** is further programmed in step **1000** to transmit the final prescribed medical regimen to the server CPU **1** for storage into the server data storage unit **2**.

In a preferred embodiment, the prescriber will be able to send to the patient more than prescription messages, such as appointment reminders or refill reminders. In addition these messages could include instructions on how to take the medication, how to conduct various medical procedures (e.g., how to clean a wound, etc.), or combinations of both. In this embodiment aider step **900**, the prescriber CPU **7** asks the computer operator whether there are any non-prescription messages. If not, then the prescriber CPU **7** is programmed to proceed to step **1000** described above. If there are non-prescription messages, then the prescriber CPU **7** is programmed to receive in step **901** the message inputted by prescriber keyboard **9**. Once the message has been inputted, the prescriber CPU **7** is programmed to produce in step **902** a schedule of non-prescription messages. After the schedule has been produced, the prescriber CPU **7** is programmed to proceed to step **1000** described above.

The Method of Utilizing the System for Patient Compliance

In the preferred embodiment, server computer station A is utilized to transmit messages to the patient. These messages will include prior notification of when and what medications the patient is scheduled to take in accordance with the prescribed medical regimen. The notification could include informing the patient of the drug name only or the drug name and the doseage to be taken at the time the patient receives the message. For example, if the patient were prescribed to take drug X three times a day, the message "take drug X now" or "take two 250 mg tablets of drug X" could be transmitted to the patient three specified times during the day. The server CPU **1** is programmed to operate in accordance with the procedure illustrated in FIG. **4**.

Server CPU **1** is programmed in step **1101** to first determine if it has received a command to stop further processing. This command is given if a fault in the system hardware or software has occurred, or if stoppage of the system is desired by the operator for any reason. If no halt command has been received, server CPU **1** is programmed in step **1102** to perform no message delivery function for a predetermined period of time. This period is to allow the prescriber to more easily and quickly access the CPU **1** to retrieve patient prescription data or pharmaceutical data, as well as to make and enter into the server data storage unit **2**, any changes to the patient prescription data. This feature becomes more important as greater number of prescribers are connected to the server CPU **1**. A preferred period of time is 30 to 60 seconds. Upon the lapse of the delay period, server CPU **1** is programmed in step **1103** to retrieve any messages that are scheduled to be transmitted within an upcoming time period. These messages are sorted by delivery time. In the event a patient has more than one message; the server CPU **1** is programmed in step **1104** to combine all of these messages into a single message for transmission to the patient.

In step **1105**, the number of messages is counted. If the number of messages is greater than one, the server CPU **1** is programmed in step **1106** to transmit through modem **5** the first message to the appropriate patient message receiving unit **13**. Step **1106** is repeated until all of the messages identified in step **1105** have been transmitted. This process is continued until there are no remaining messages to be transmitted. The server CPU **1** is then programmed to again determine if a halt command has been received. The procedure is then continued as before.

The patient message receiving unit **13** upon receiving a message is activated to call the patient's pager and deliver the message. If the pager **14** is a two-way pager, the patient will have been instructed to acknowledge receipt of the message. If the message is more than notification to take medication, the patient can also respond to any queries that may be included in the message. In this event, the server CPU **1** is programmed to search at step **1108** for these reply messages when the message count if greater than one. The collected messages are then transmitted at step **1109** to be processed by the server. There are of course many alternative procedures for routing the patient's response to the prescriber. For example, patient message receiving unit **13** may be directly connected to prescriber modem **12**. In another alternative route, modem **5** can be directly connected to prescriber modem **12**.

The Method of Utilizing the System for Prescription Delivery

In this embodiment, the prescriber CPU **7** is programmed to transmit, via prescriber modem **12**, the patient prescriptions to the server CPU **1**. The server CPU **1** is also programmed to transmit using commercially available communications software these patient prescriptions to the prescription delivery system D.

Prescription delivery system CPU **18** is programmed to retrieve drug cost data stored in its data storage units. This data is then collated to the drugs contained in the prescriptions in order to generate an invoice and other desired documentation which is then produced by printing unit **19** to be included with the prescriptions when delivered to the patient.

The Method of Utilizing the System for Prescription Payment

If the patient will be the person paying for the prescriptions, then the invoice generated by the prescription delivery system D will be delivered to the patient.

If the payor is the patient, a healthcare payor, or government agency, the invoice generated by the prescription delivery system D will be delivered, preferably modemed, to the payor system E for payment. In an alternate preferred embodiment, the invoice delivery could be conducted electronically or optically. In this embodiment the invoice will be transmitted through server computer station A to payor system E. This can be achieved through any number of readily available commercial communications software programs. In another alternate preferred embodiment, the prescription delivery system D will directly communicate by well known linked computer systems to payor system E.

A copy of a preferred software program for use with the system and method of this invention is set forth in Exhibit 1.

There are of course other alternate embodiments which are obvious from the foregoing descriptions of the invention which are intended to be included within the scope of the invention as defined by the following claims.

What is claimed is:

1. A system to facilitate compliance with a prescribed medical regimen comprising:

(a) a computer system having a data storage unit capable of storing patient data and patient prescription data;

(b) a central processing unit programmed and operatively connected to said data storage unit to store said patient data and said patient prescription data in said data storage unit;

(c) wherein said system includes a program to generate and transmit from a patient prescription a patient message, wherein said patient message includes a drug to be administered by a patient at a time of receiving said patient message in order that said patient complies with said patient prescription;

(d) a message transmitting unit operatively connected to said central processing unit and transmitting said patient message at a time proximate to when said patient is scheduled to administer a unit dosage; and

(e) an addressable communication device allowing said patient to receive said patient message transmitted from said transmitting unit.

2. A system according to claim 1, wherein:

(a) said data storage unit is further capable of storing pharmaceutical data; and

(b) said program stored in said central processing unit allows comparison of said patient prescription data to said patient data and said pharmaceutical data to determine if said patient prescription data is within recommended daily and unit dosage ranges.

3. A system according to claim 2, wherein said determination of whether said patient prescription data is within said recommended daily and unit dosage ranges is transmitted to a reporting unit.

4. A system according to claim 2, wherein said program stored in said central processing unit:

(a) allows comparison of said patient data and patient prescription data to determine if said patient prescription data is within a recommended prescribing duration range as defined by said pharmaceutical data; and

(b) transmits the determination to a reporting unit.

5. A system according to claim 2, wherein:

(a) said system includes a program to generate and transmit a prescription invoice; and

(b) said system further comprises a payment system operatively connected to said central processing unit to receive said prescription invoice.

6. A system according to claim 1, wherein:

(a) said data storage unit is further capable of storing pharmaceutical data; and

(b) said program stored in said central processing unit:

(i) allows comparison of said patient data and patient prescription data to determine if said patient prescription data is within a recommended prescribing duration range as defined by said pharmaceutical data; and

(ii) transmits the determination to a reporting unit.

7. A system according to claim 1, wherein:

(a) said system includes a program to generate and transmit a prescription invoice; and

(b) said system further comprises a payment system operatively connected to said central processing unit to receive said prescription invoice.

8. A system according to claim 1, further comprising a message receiving unit, including a modem and operatively connected to said transmitting unit to transmit said patient message to a pager.

9. A system according to claim 8, wherein said pager is a two way pager.

10. A system according to claim 1, wherein said system further includes:

(a) pharmaceutical data stored in said data storage unit; and

(b) said program further:

(i) compares said patient prescription data to said pharmaceutical data to determine if said patient prescription data indicates that unacceptable drug interactions will occur from the drugs included within said medical regimen; and

(ii) transmits the determination to a reporting unit.

11. A system according to claim 1, wherein said system further includes a program to:

(a) compare said patient prescription data to said patient data to determine if there were reported prior drug reactions to any of the drugs included within said medical regimen, and (b) transmit the determination to a reporting unit.

12. A system according to claim 1, wherein:

(a) said data storage unit is further capable of storing pharmaceutical data, including a recommended dosage range for at least some of the drug included in said pharmaceutical data; and

(b) said program determines if said dosage is within said recommended dosage range and transmits the determination to a reporting unit.

13. A system according to claim 12 wherein if said program determines said dosage is not within said recommended dosage range; said program:

(a) amends said dosage to be within said recommended dosage range;

(b) transmits said amended dosage to said central processing unit for storage in said data storage unit;

(c) retrieves from said data storage unit said amended dosage prior to the time said patient is to administer said drug; and

(d) notifies said patient as to when and how much of said drug to administer.

14. A system according to claim 1 wherein:

(a) said patient data comprises:

(i) a patient identification code used to identify said patient,

(ii) data necessary to determine age of said patient, and

(iii) a listing of other medications which said patient may be taking; and

(b) said patient prescription data comprises:

(i) a prescription identification code used to identify a medication to be prescribed,

(ii) a prescription dosage of said medication to be used in said medical regimen,

(iii) a duration period of taking said medication to be used in said medical regimen, and

(iv) a frequency schedule of taking a prescribed amount of said dosage in said medical regimen.

15. A system according to claim 1 wherein said data storage unit is further capable of storing pharmaceutical data and said pharmaceutical data comprises:

(i) a listing of identification codes used to identify medications,

(ii) for each medication in said listing, a recommended dosage range, a recommended duration range, a maintenance dosage range, and an acute dosage range, and

(iii) for each medication contained in said listing, known interactions of each of said medications with other medications contained in said listing.

16. A system according to claim **1** wherein:

(a) said data storage unit is further capable of storing pharmaceutical data; and

(b) said program:

(i) compares said patient prescription data to said pharmaceutical data to determine if said drug to be prescribed has one or more known drug interactions with other medication said patient is taking; and

(ii) transmits a report to a prescribing physician if a known drug interactions exist.

17. A system according to claim **16**, wherein said program:

(a) amends said patient prescription data to eliminate said drug interaction if a known drug interactions exist; and

(b) transmits said amended prescription data to said central processing unit.

18. A system according to claim **1**, wherein said addressable communications device is a pager.

19. A system according to claim **1**, wherein said addressable communications device is a remote communications device.

20. A system according to claim **1**, wherein said addressable communications device is a wireless communications device.

* * * * *

US006370841B1

(12) **United States Patent**
Chudy et al.

(10) **Patent No.: US 6,370,841 B1**
(45) **Date of Patent: Apr. 16, 2002**

(54) **AUTOMATED METHOD FOR DISPENSING BULK MEDICATIONS WITH A MACHINE-READABLE CODE**

(75) Inventors: **Duane S. Chudy**, Lincolnshire; **Richard A. Jobus**, Crystal Lake; **David A. Schultz**, Palatine, all of IL (US)

(73) Assignee: **AutoMed Technologies, Inc.**, Vernon Hills, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/454,042**

(22) Filed: **Dec. 3, 1999**

(51) **Int. Cl.**[7] **B65B 61/02**; B65B 59/00

(52) **U.S. Cl.** **53/411**; 53/415; 53/445; 53/474; 221/10; 700/235

(58) **Field of Search** 53/411, 415, 445, 53/474, 131.2–131.5, 136.1, 155, 168, 238, 239; 221/10; 700/235

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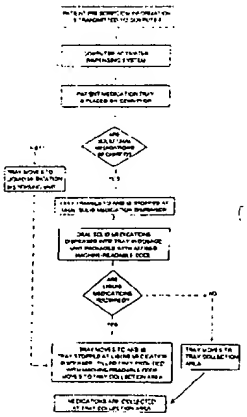
Primary Examiner—Stephen F. Gerrity
(74) *Attorney, Agent, or Firm*—Jansson, Shupe & Munger, Ltd.

(57) **ABSTRACT**

An improved automated method for dispensing bulk medications with machine-readable code. The method includes dispensing oral solid and liquid unit-of-use medications in unit dosage amounts. The medications are dispensed with machine-readable information which is generated as the medication is dispensed. The machine-readable information is patient- specific and can be customized to suit the needs of the operator. The machine-readable information can be used to monitor and control the medication from the time it is dispensed through to the time it is taken by the patient.

35 Claims, 26 Drawing Sheets



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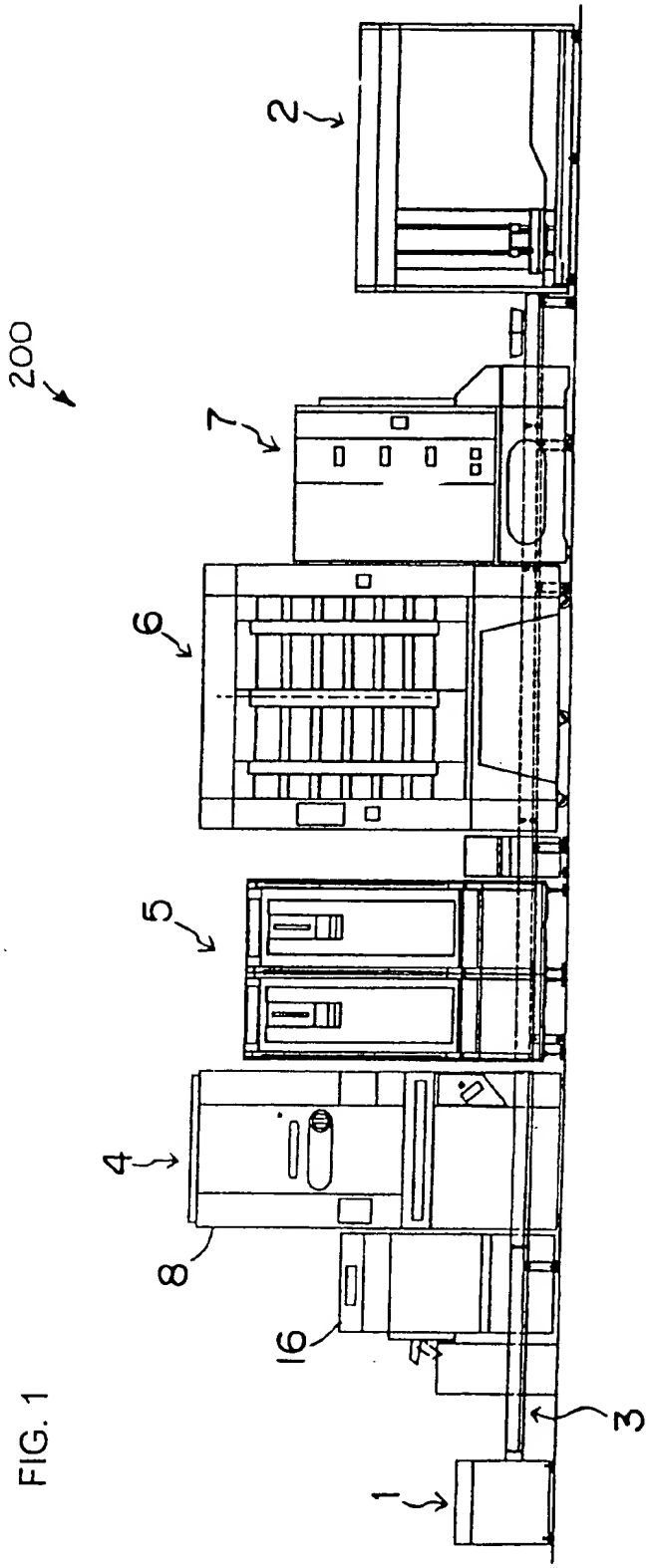


FIG. 1

FIG. 2A

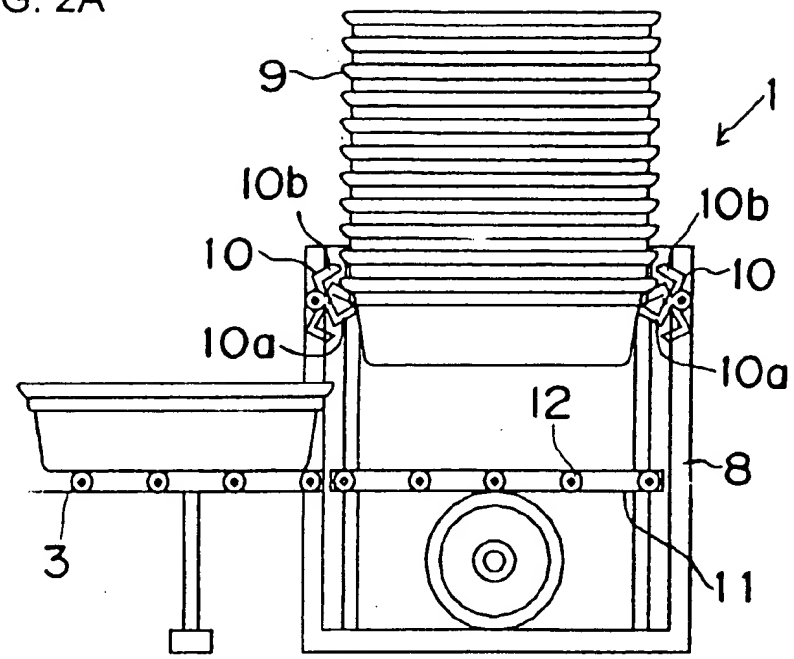


FIG. 2B

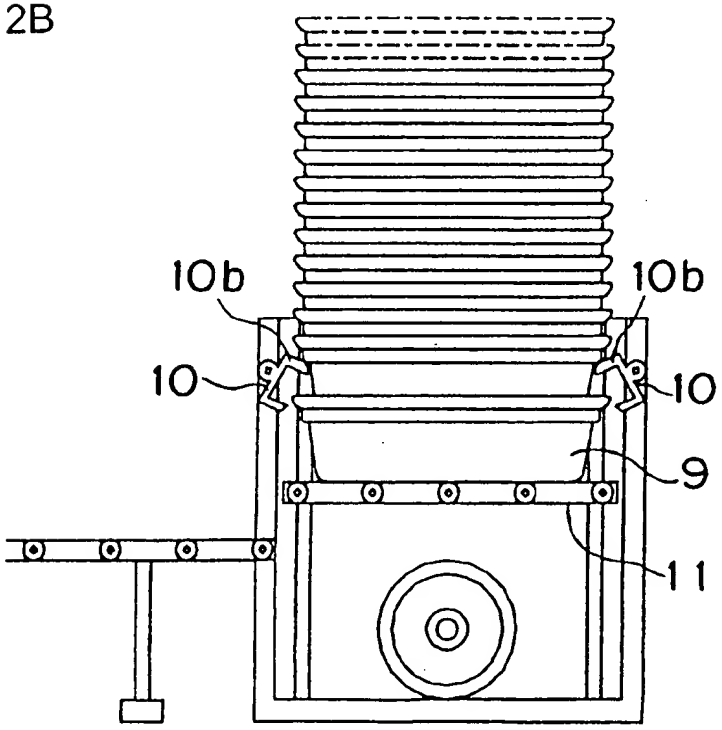


FIG. 3

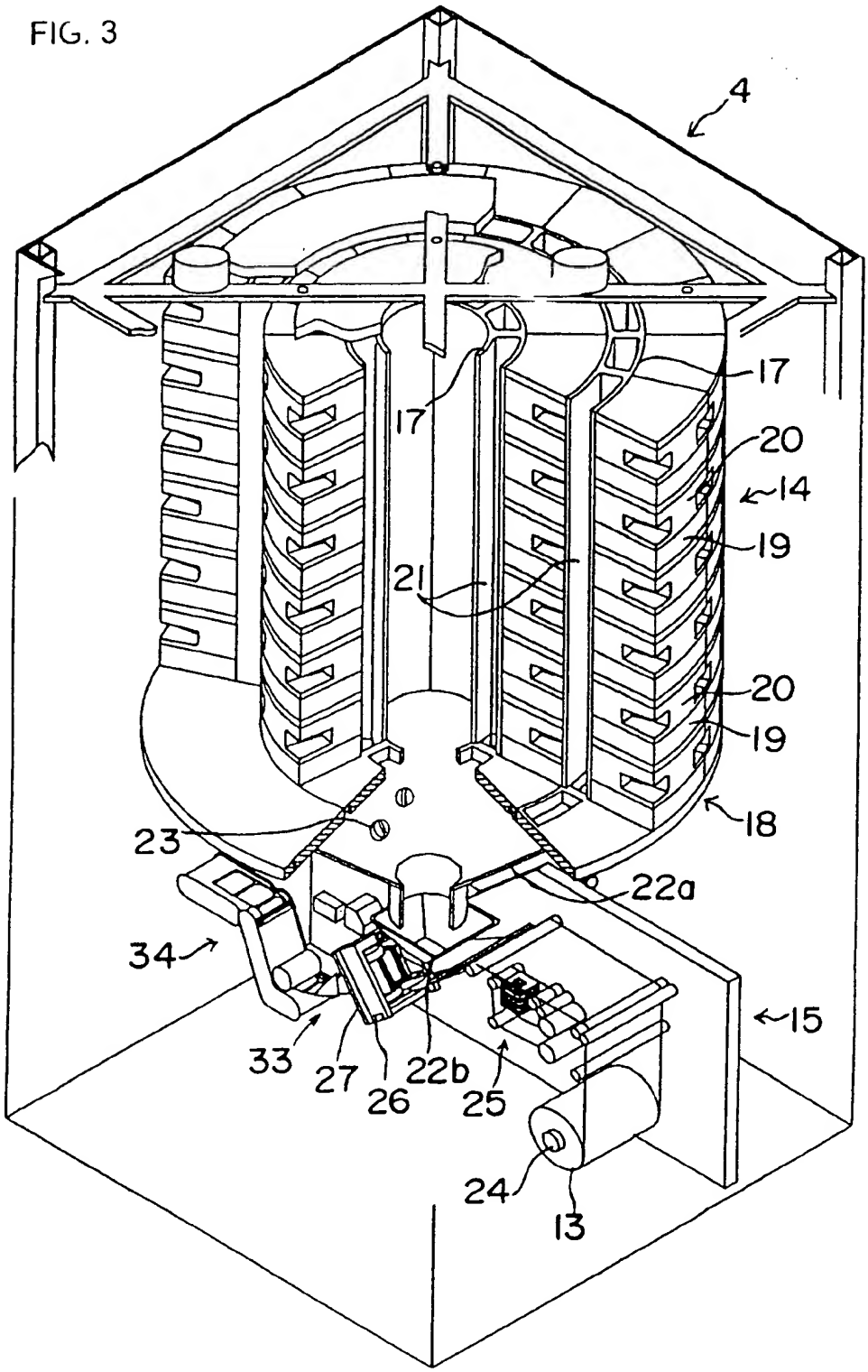


FIG. 4

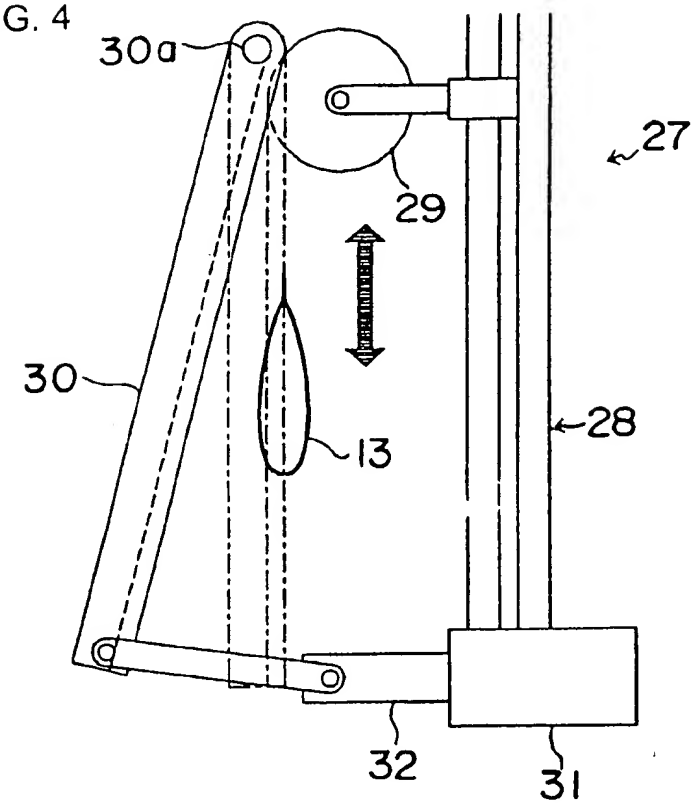


FIG. 5

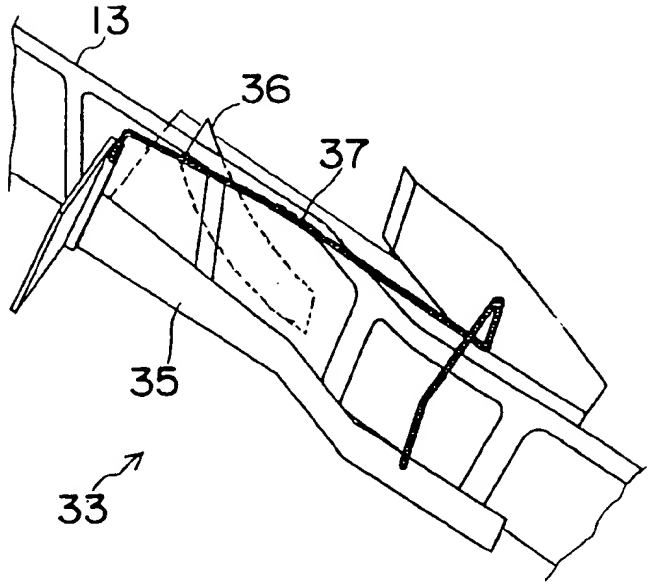


FIG. 6

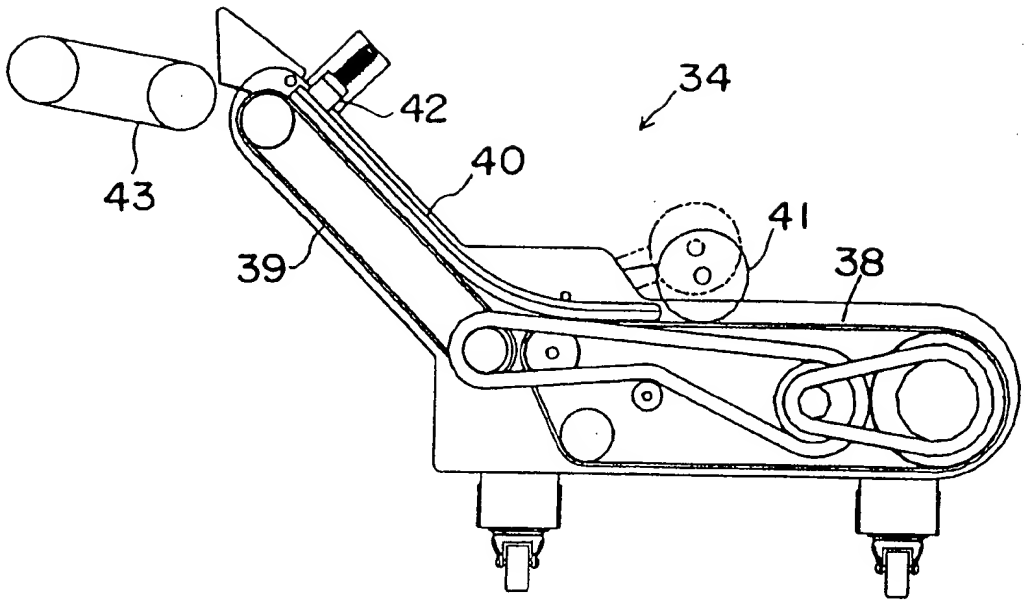


FIG. 7

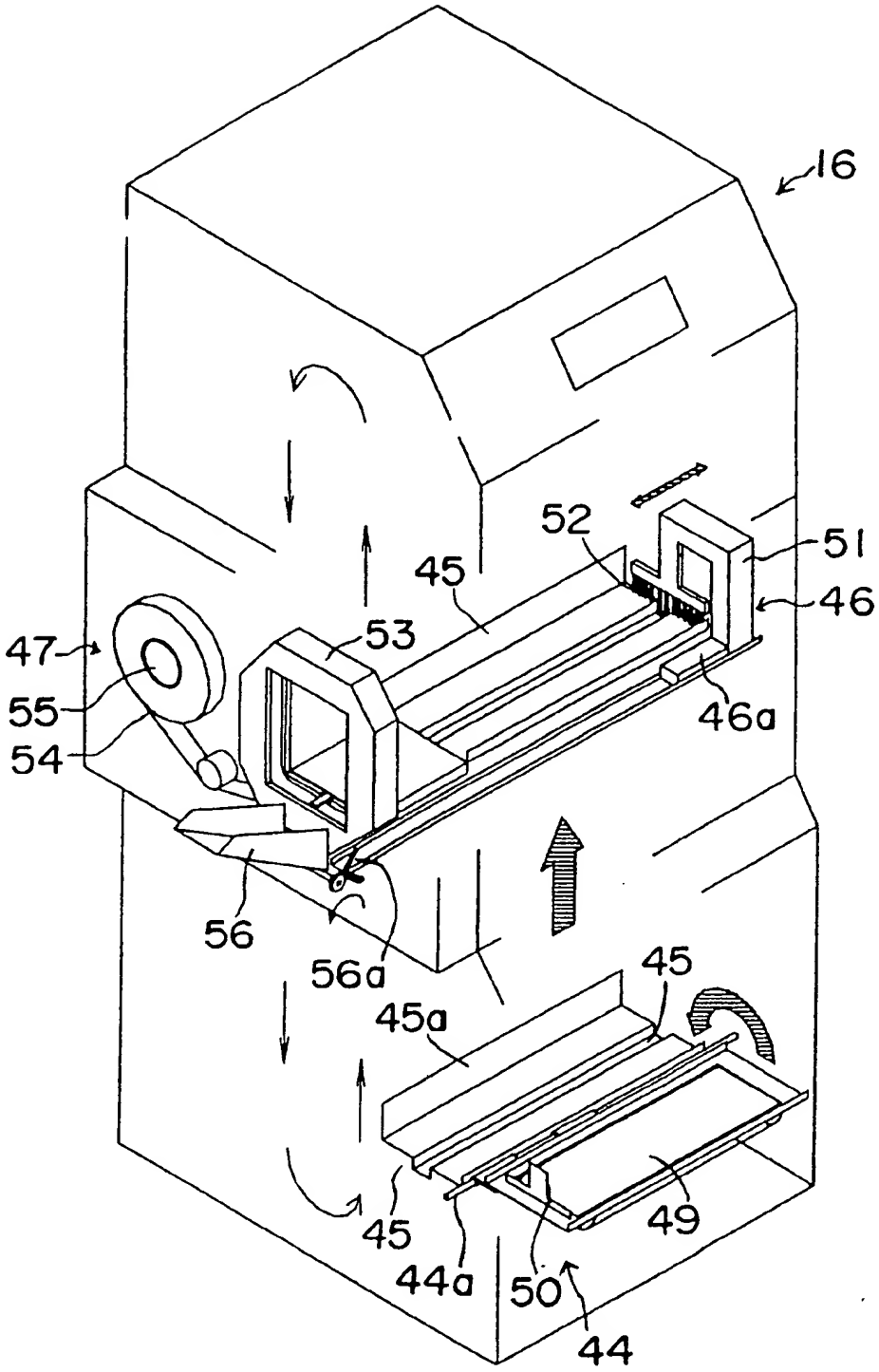


FIG. 8

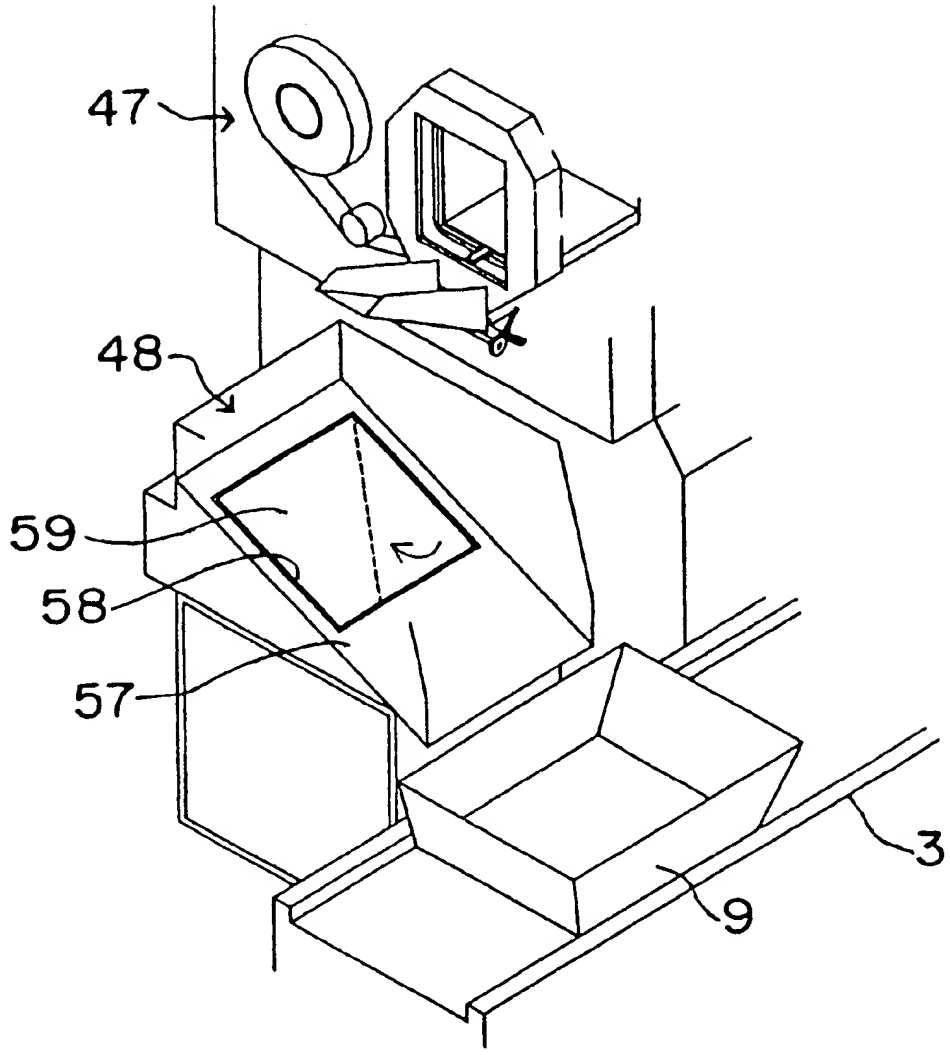


FIG. 9

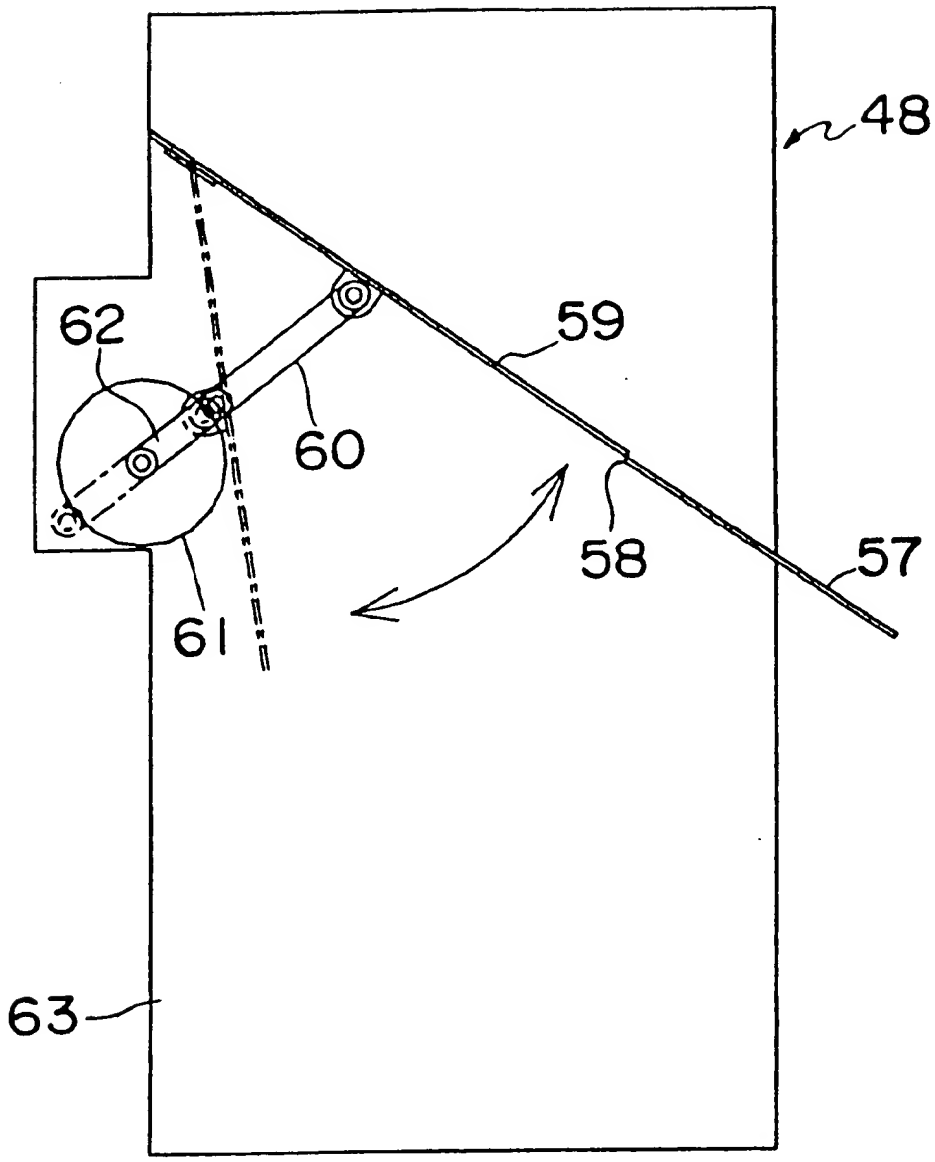


FIG. 10

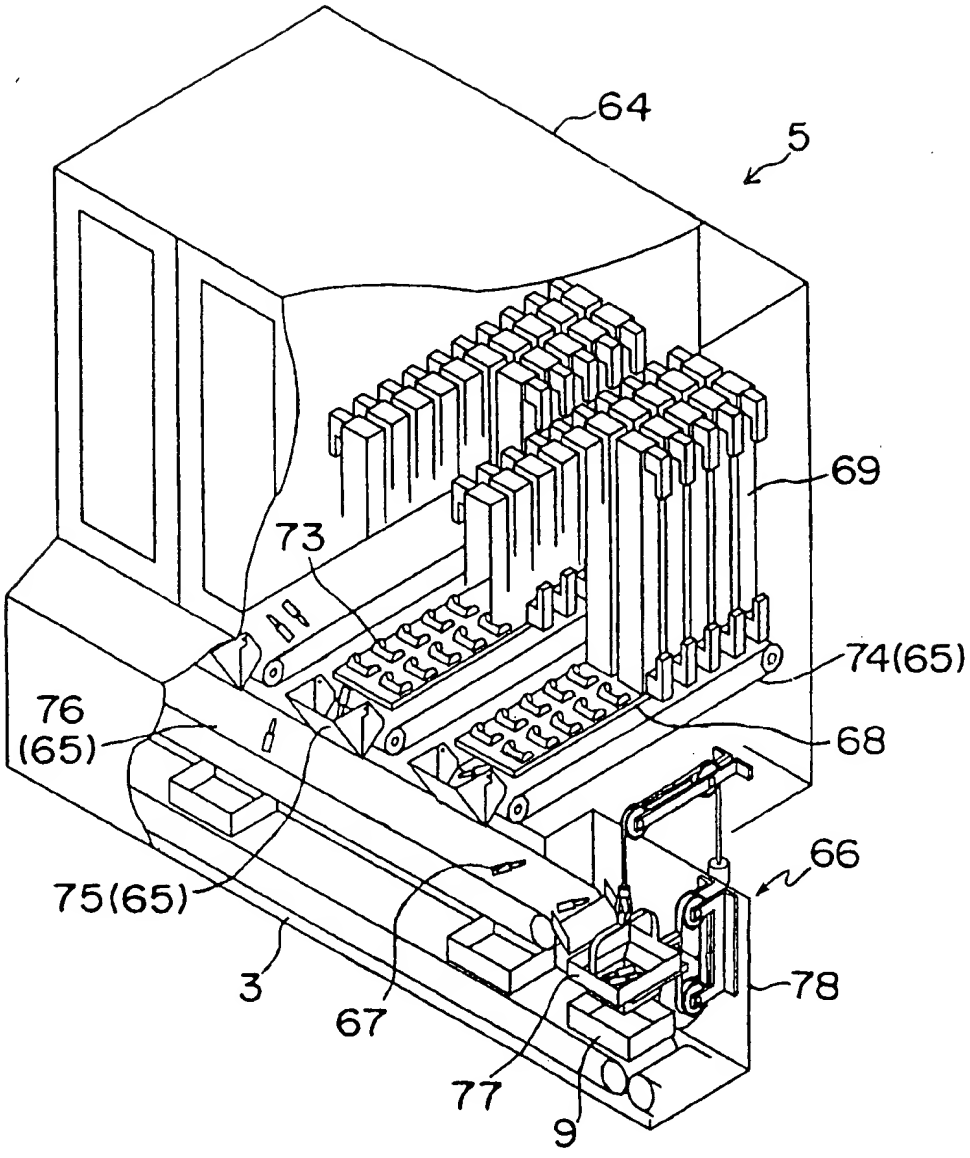


FIG. 11A

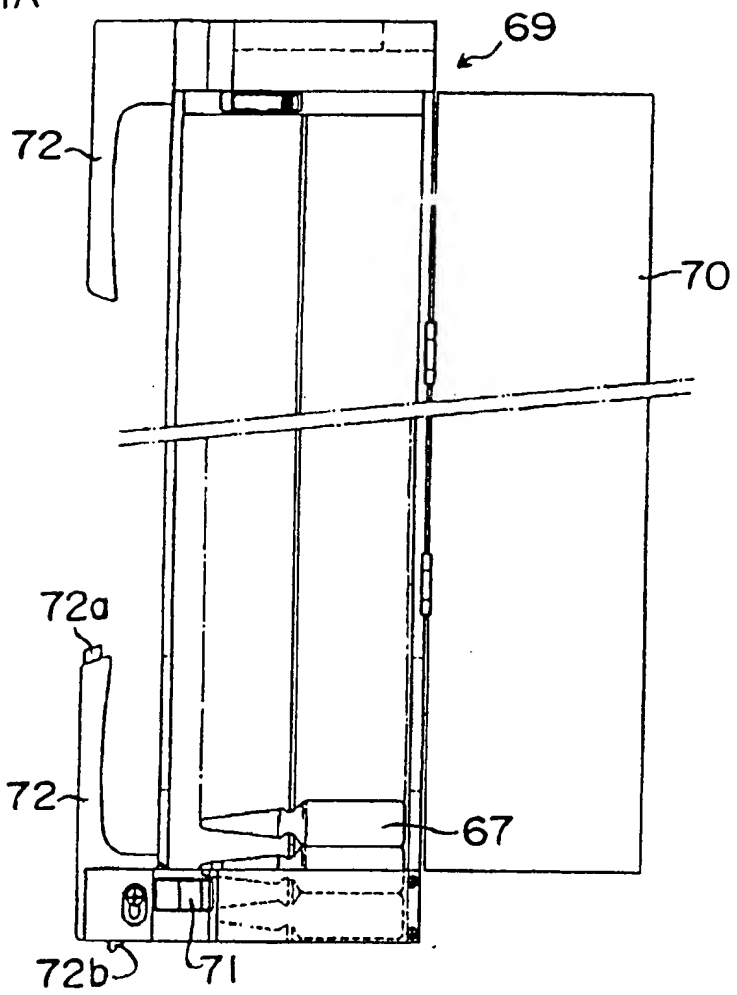


FIG. 11B

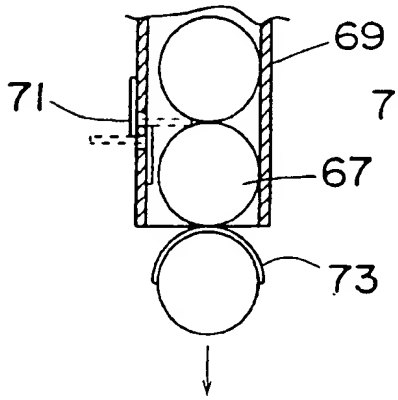


FIG. 11C

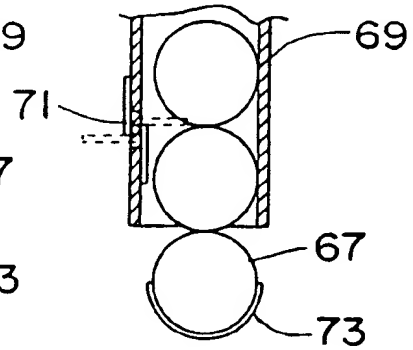


FIG. 12

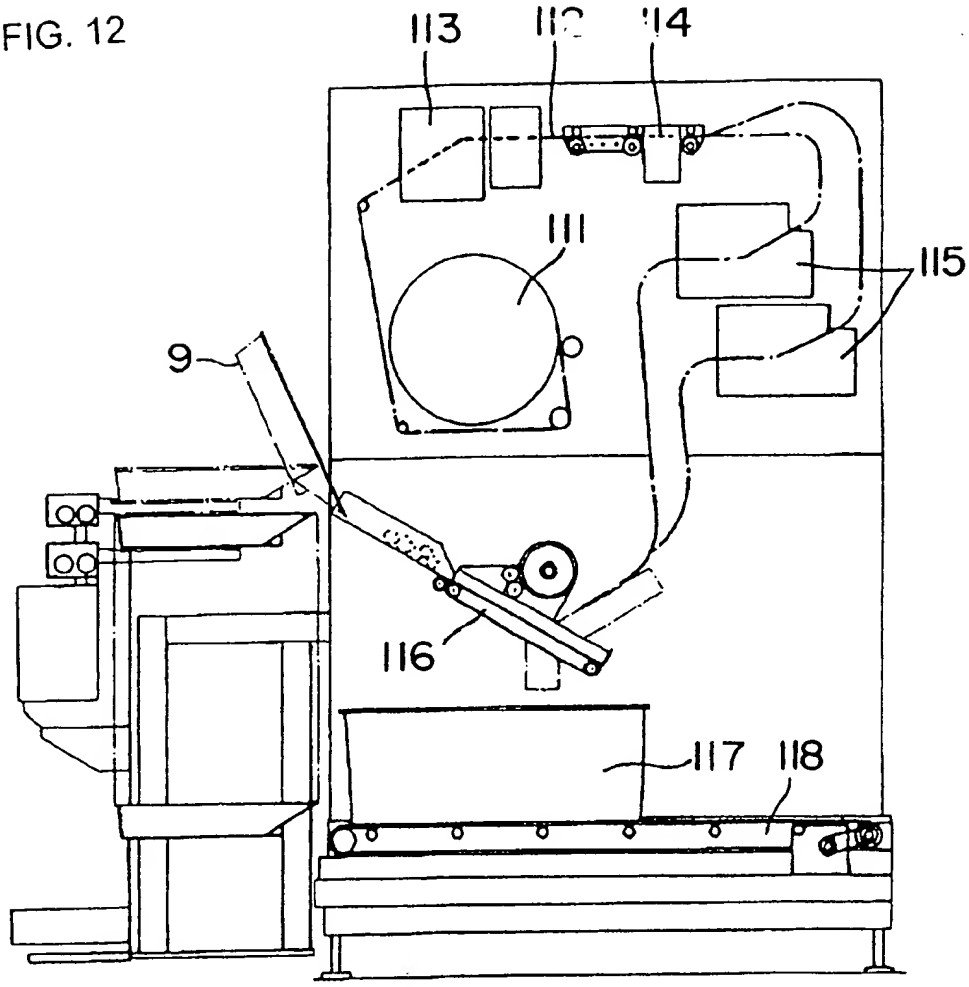


FIG. 13A

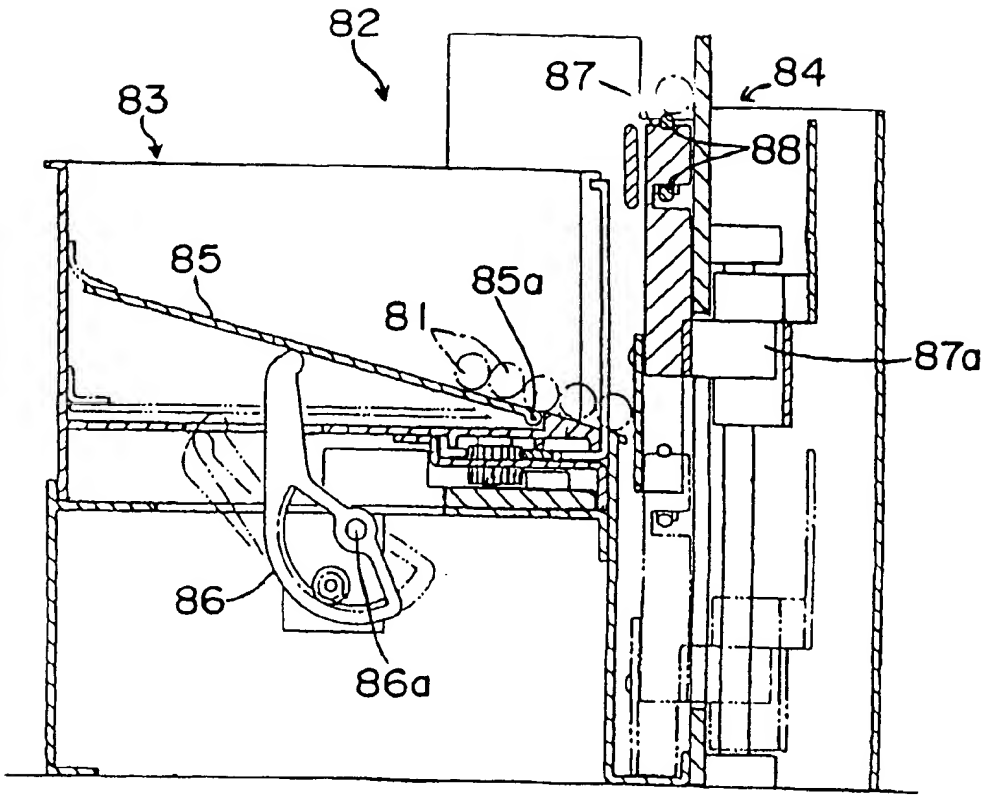
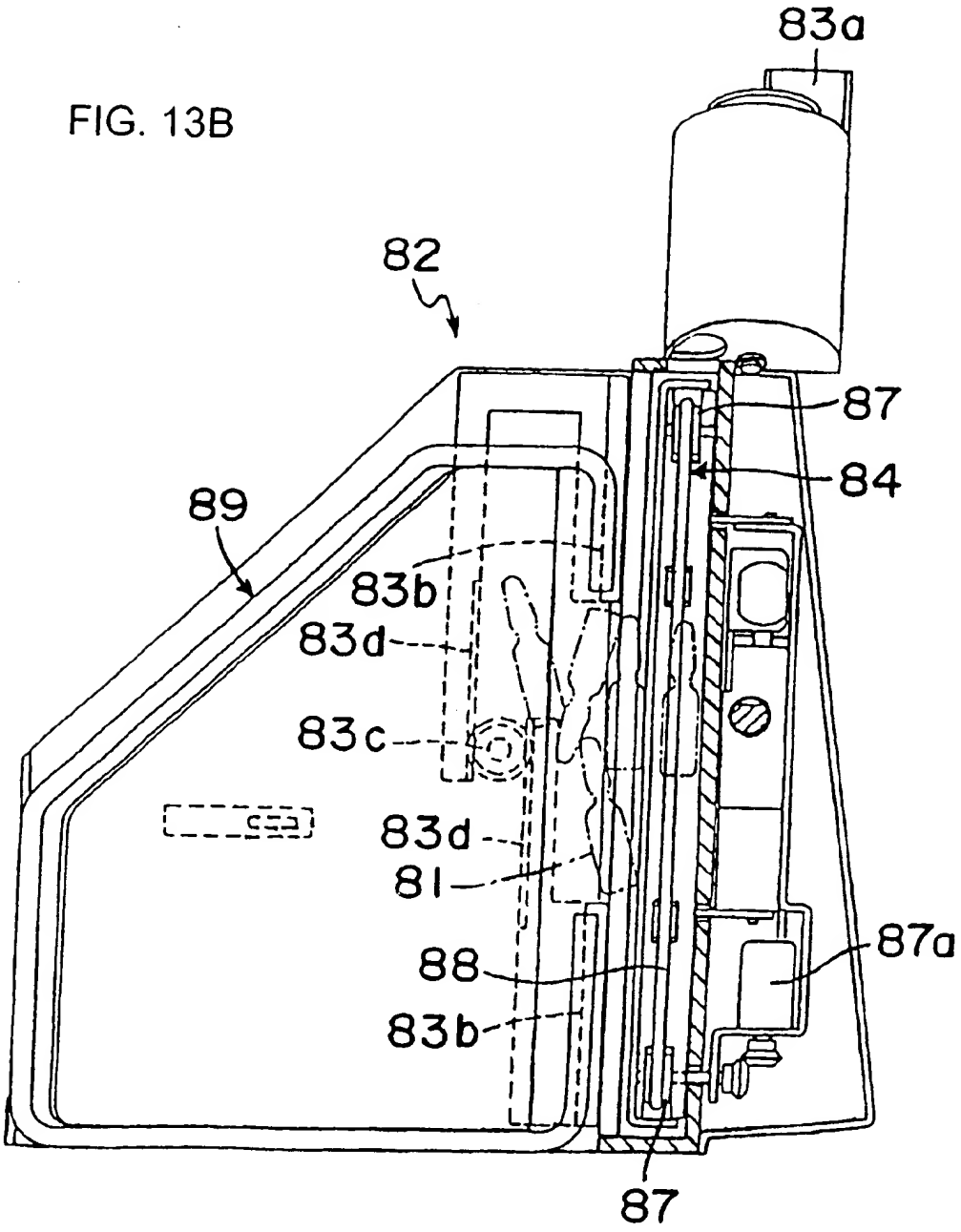


FIG. 13B



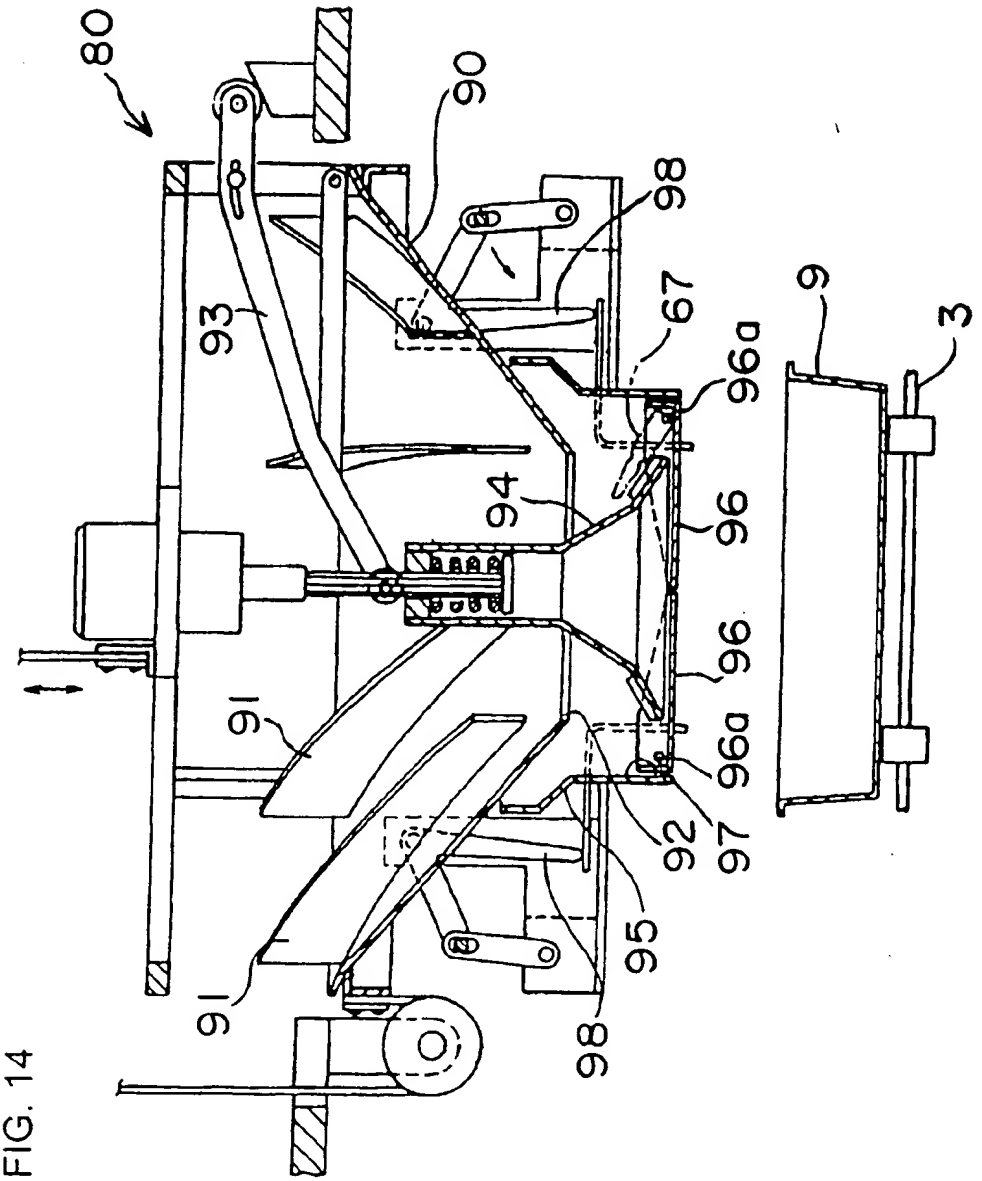


FIG. 14

FIG. 15A

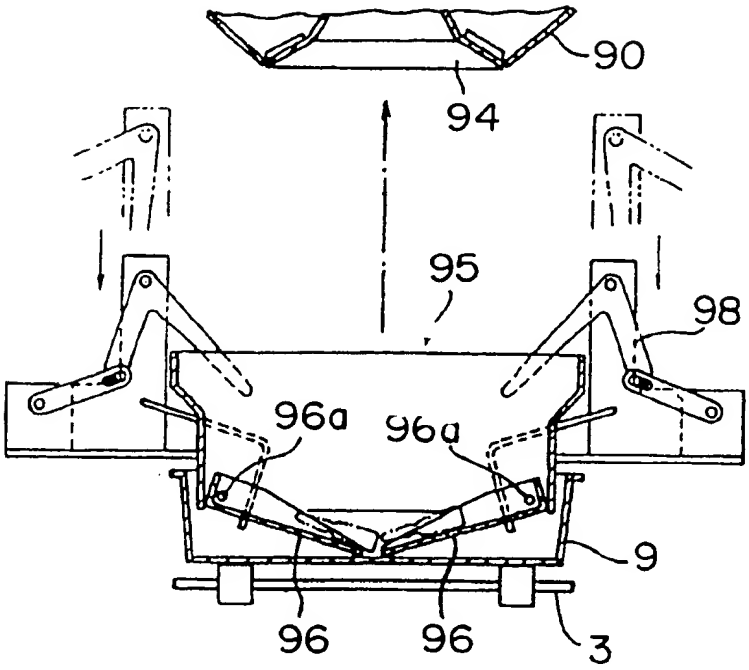


FIG. 15B

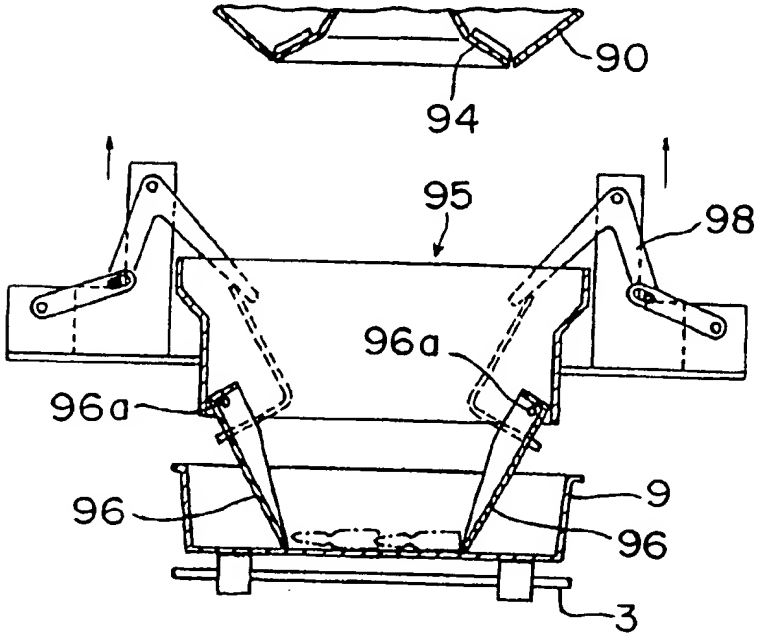
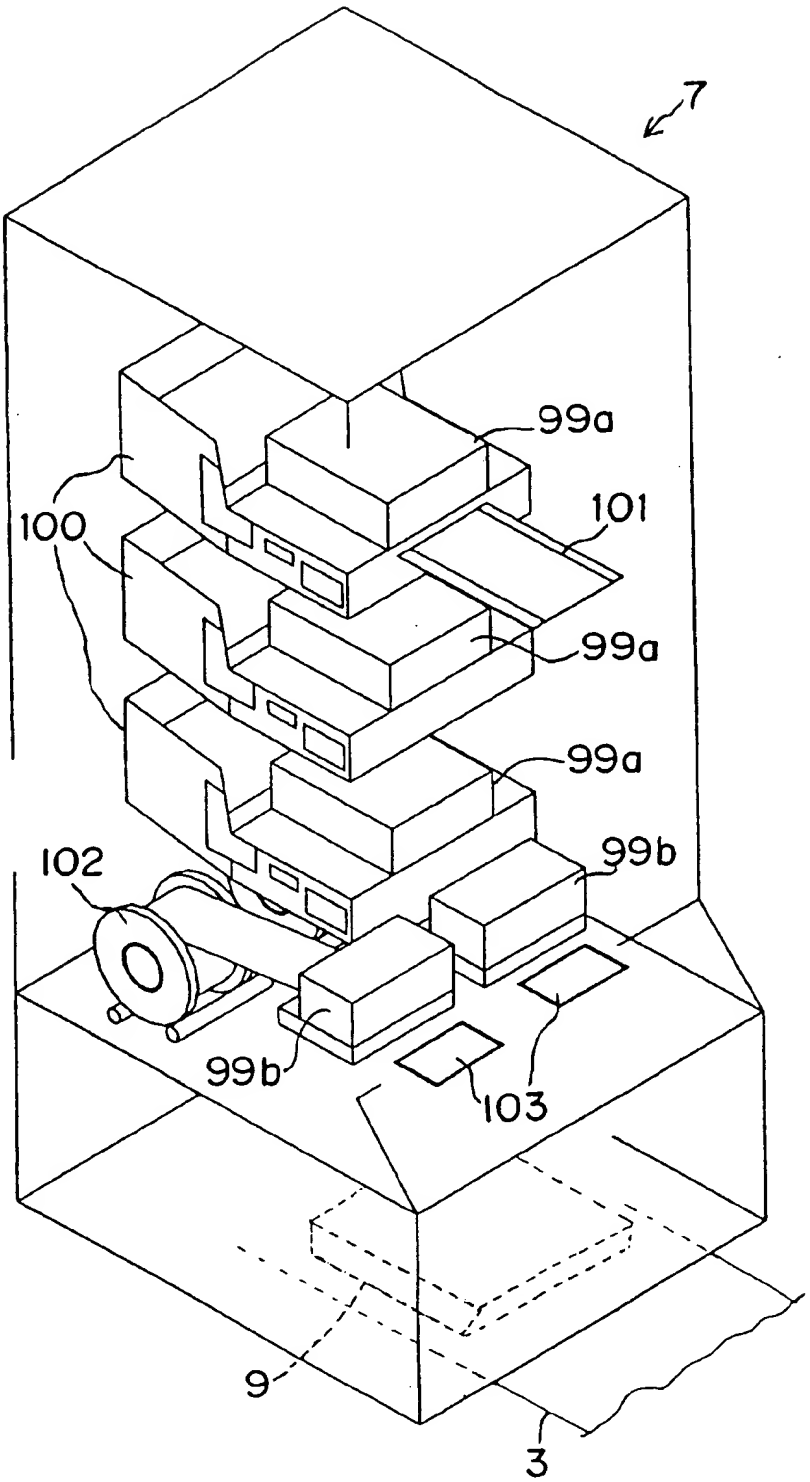
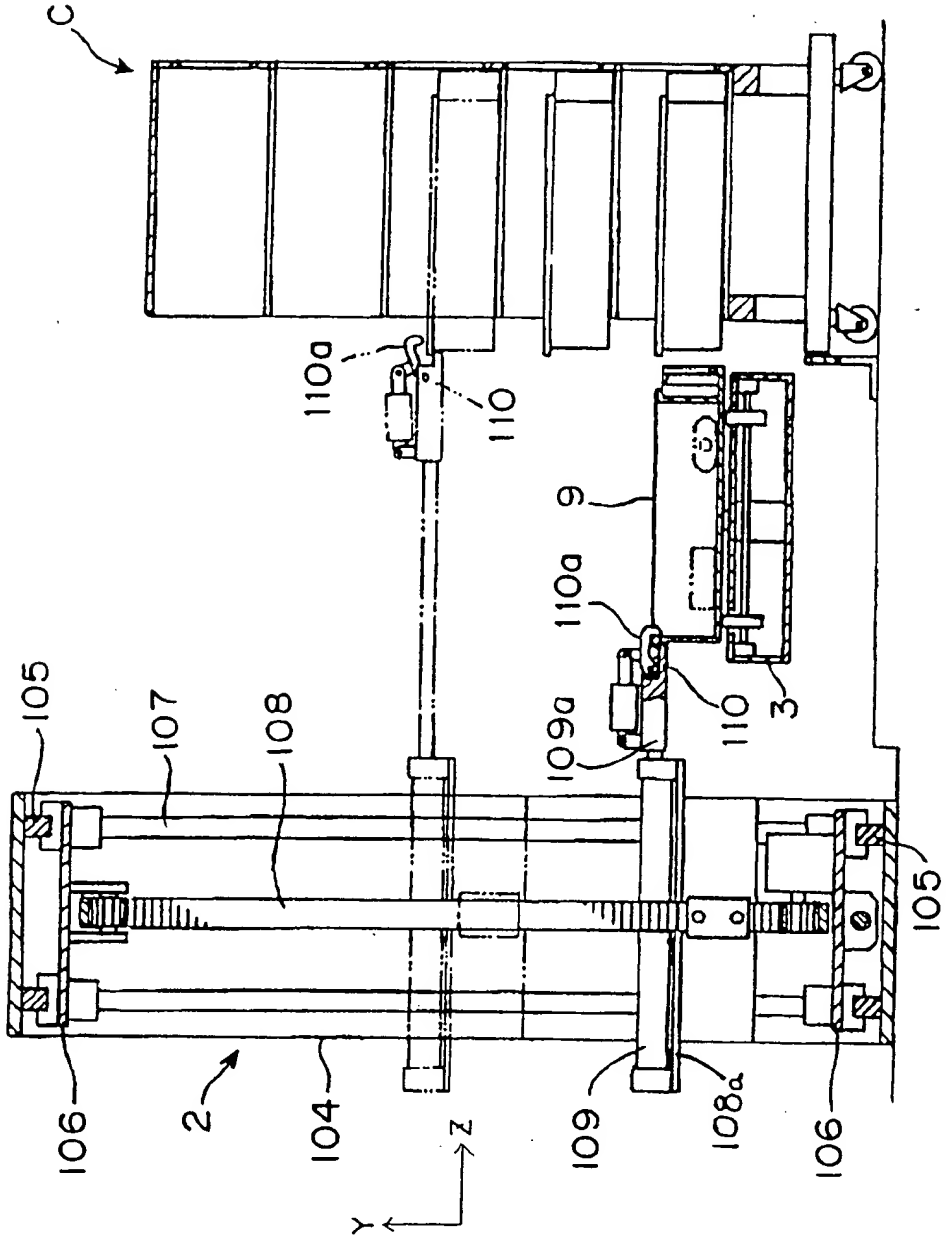


FIG. 16




C
110a
110
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106
Z
Y

FIG. 17

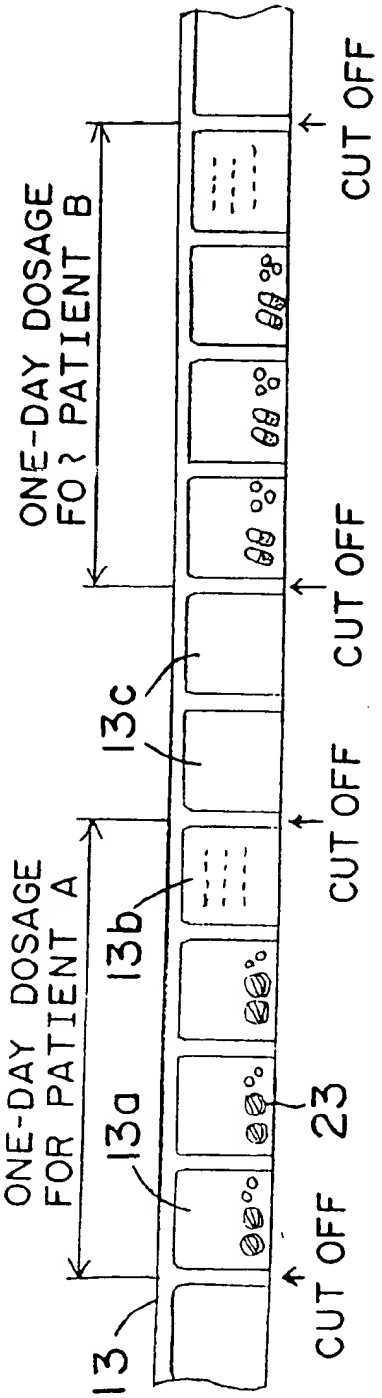


FIG. 18A

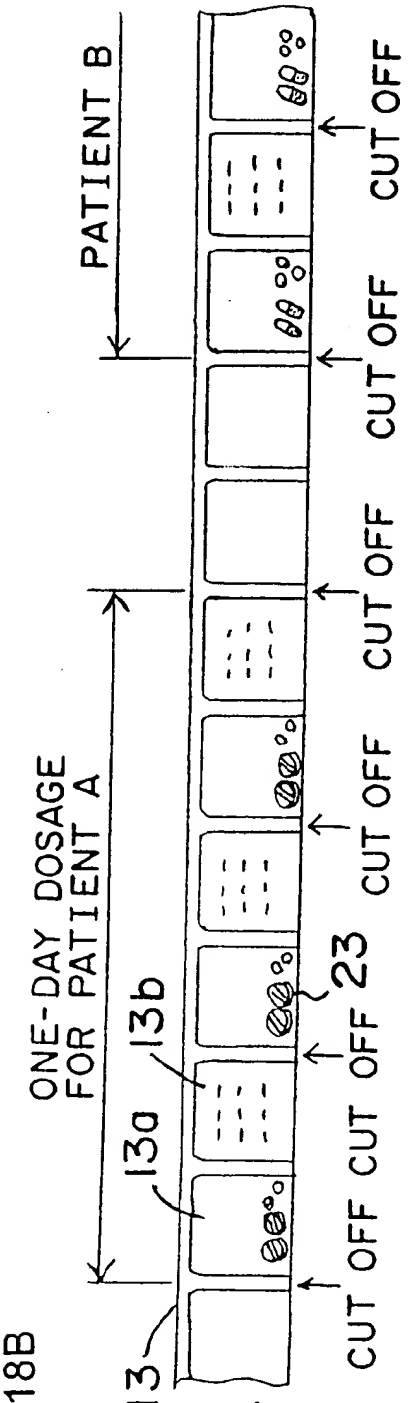


FIG. 18B

Fig. 19A

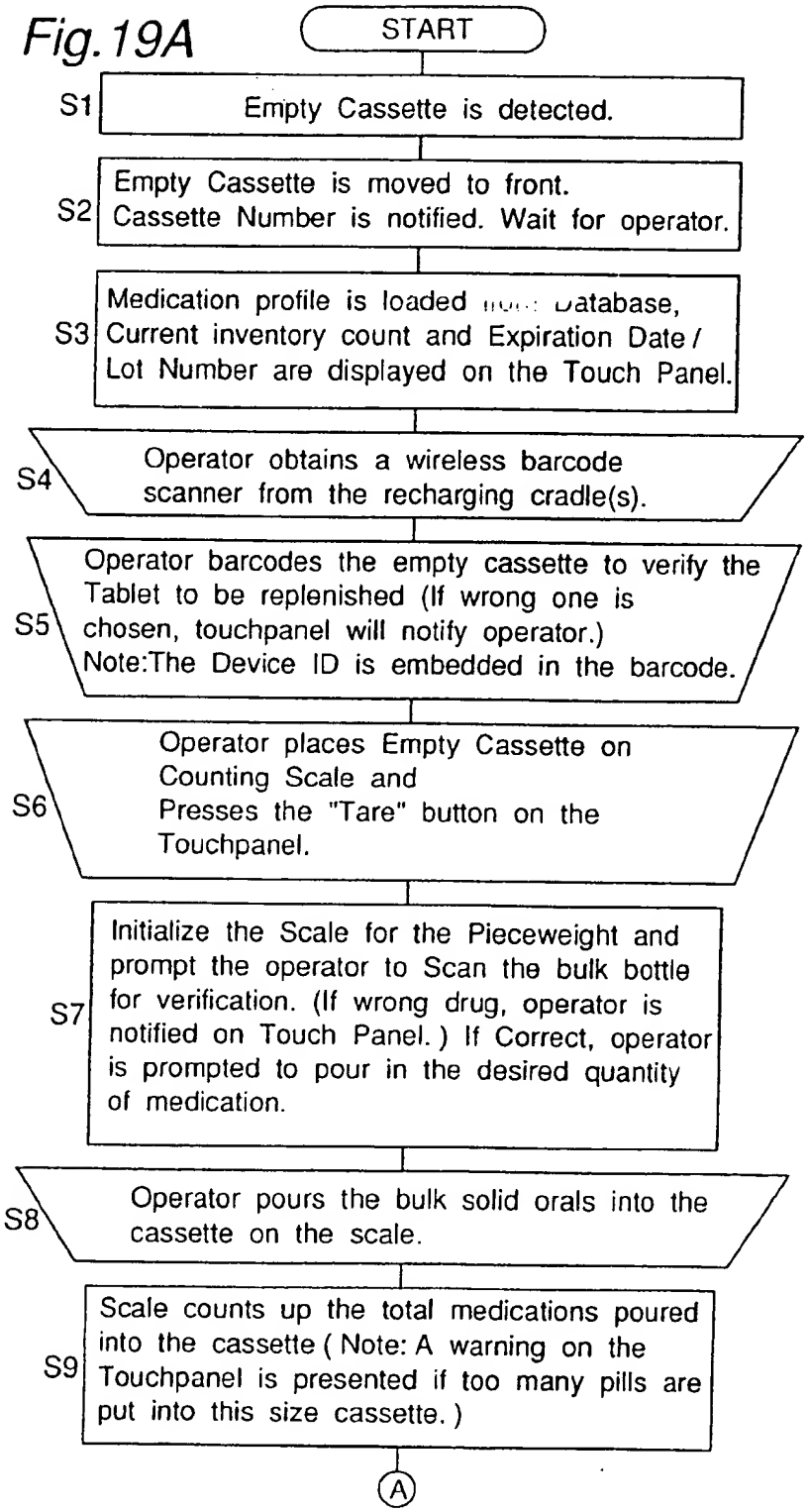

START
S1
Empty Cassette is detected.
S2
Empty Cassette is moved to front.
Cassette Number is notified. Wait for operator.
S3
Medication profile is loaded from Database,
Current inventory count and Expiration Date / Lot Number are displayed on the Touch Panel.
S4
Operator obtains a wireless barcode scanner from the recharging cradle(s).
S5
Operator barcodes the empty cassette to verify the Tablet to be replenished (If wrong one is chosen, touchpanel will notify operator.)
Note:The Device ID is embedded in the barcode.
S6
Operator places Empty Cassette on Counting Scale and
Presses the "Tare" button on the Touchpanel.
S7
Initialize the Scale for the Pieceweight and prompt the operator to Scan the bulk bottle for verification. (If wrong drug, operator is notified on Touch Panel.) If Correct, operator is prompted to pour in the desired quantity of medication.
S8
Operator pours the bulk solid orals into the cassette on the scale.
S9
Scale counts up the total medications poured into the cassette (Note: A warning on the Touchpanel is presented if too many pills are put into this size cassette.)
A

Fig. 19B

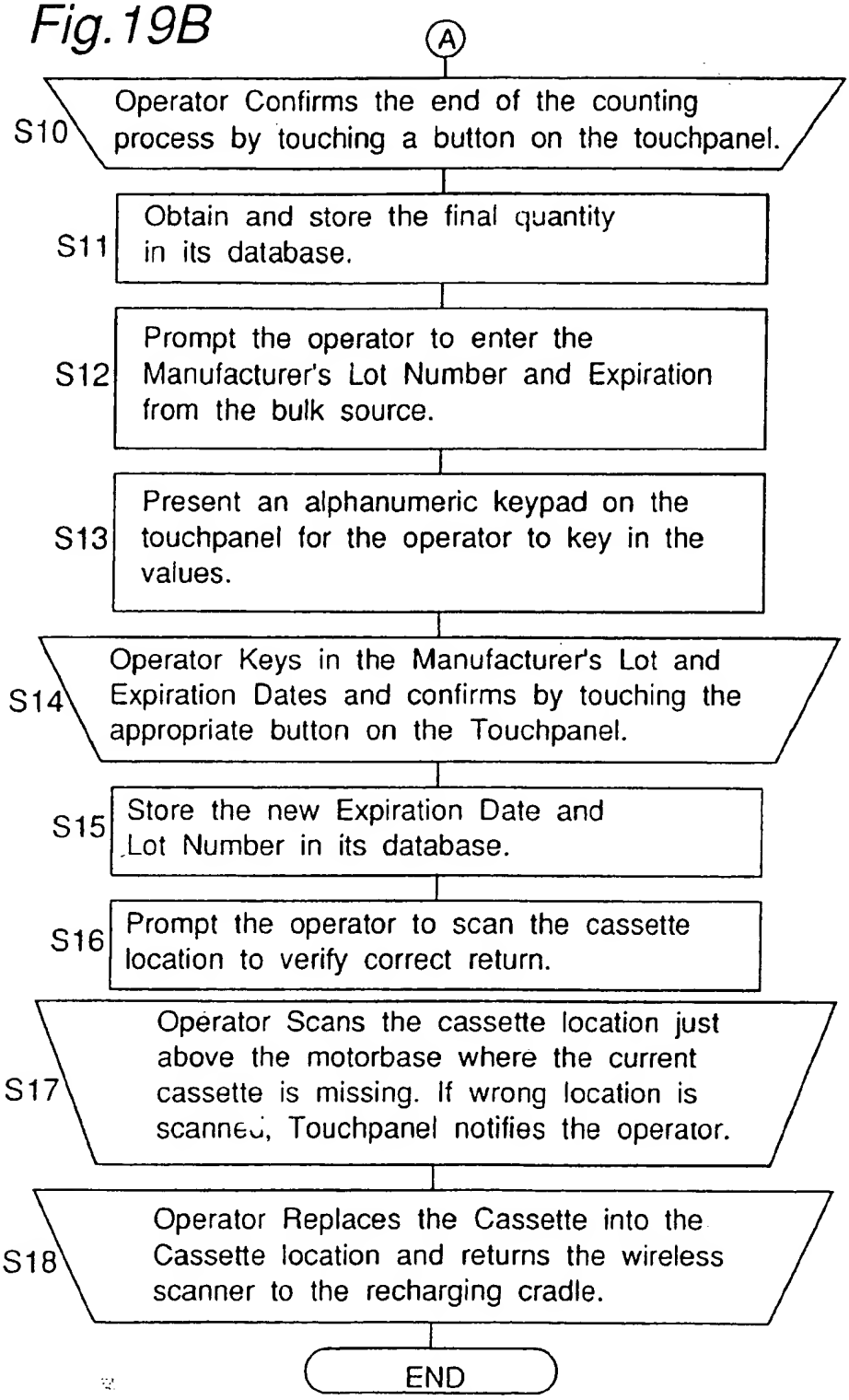

A
S10
Operator Confirms the end of the counting process by touching a button on the touchpanel.
S11
Obtain and store the final quantity in its database.
S12
Prompt the operator to enter the Manufacturer's Lot Number and Expiration from the bulk source.
S13
Present an alphanumeric keypad on the touchpanel for the operator to key in the values.
S14
Operator Keys in the Manufacturer's Lot and Expiration Dates and confirms by touching the appropriate button on the Touchpanel.
S15
Store the new Expiration Date and Lot Number in its database.
S16
Prompt the operator to scan the cassette location to verify correct return.
S17
Operator Scans the cassette location just above the motorbase where the current cassette is missing. If wrong location is scanned, Touchpanel notifies the operator.
S18
Operator Replaces the Cassette into the Cassette location and returns the wireless scanner to the recharging cradle.
END

Fig.20A

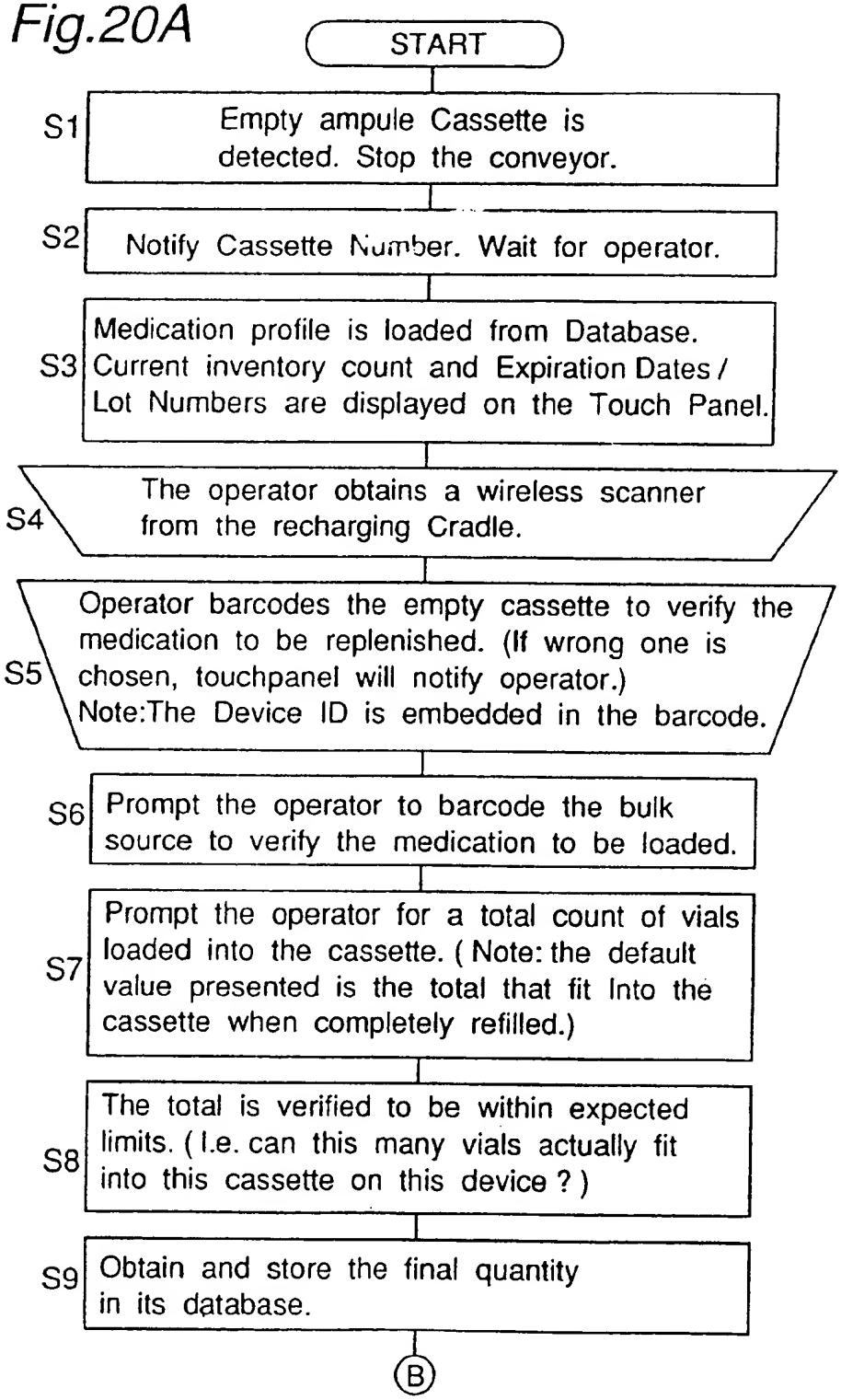

START
S1
Empty ampule Cassette is detected. Stop the conveyor.
S2
Notify Cassette Number. Wait for operator.
S3
Medication profile is loaded from Database. Current inventory count and Expiration Dates / Lot Numbers are displayed on the Touch Panel.
S4
The operator obtains a wireless scanner from the recharging Cradle.
S5
Operator barcodes the empty cassette to verify the medication to be replenished. (If wrong one is chosen, touchpanel will notify operator.) Note:The Device ID is embedded in the barcode.
S6
Prompt the operator to barcode the bulk source to verify the medication to be loaded.
S7
Prompt the operator for a total count of vials loaded into the cassette. (Note: the default value presented is the total that fit Into the cassette when completely refilled.)
S8
The total is verified to be within expected limits. (I.e. can this many vials actually fit into this cassette on this device ?)
S9
Obtain and store the final quantity in its database.
B

Fig.20B

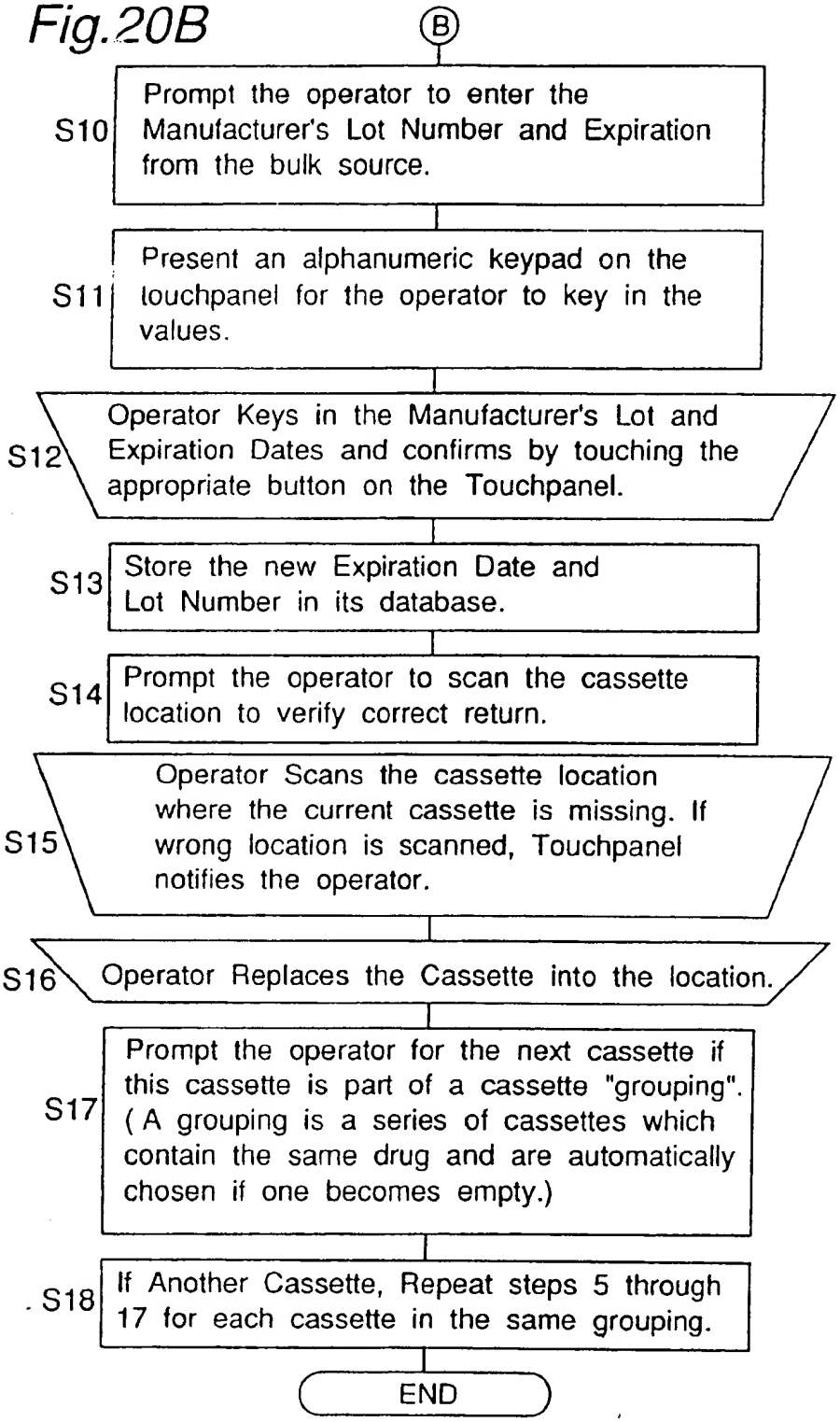
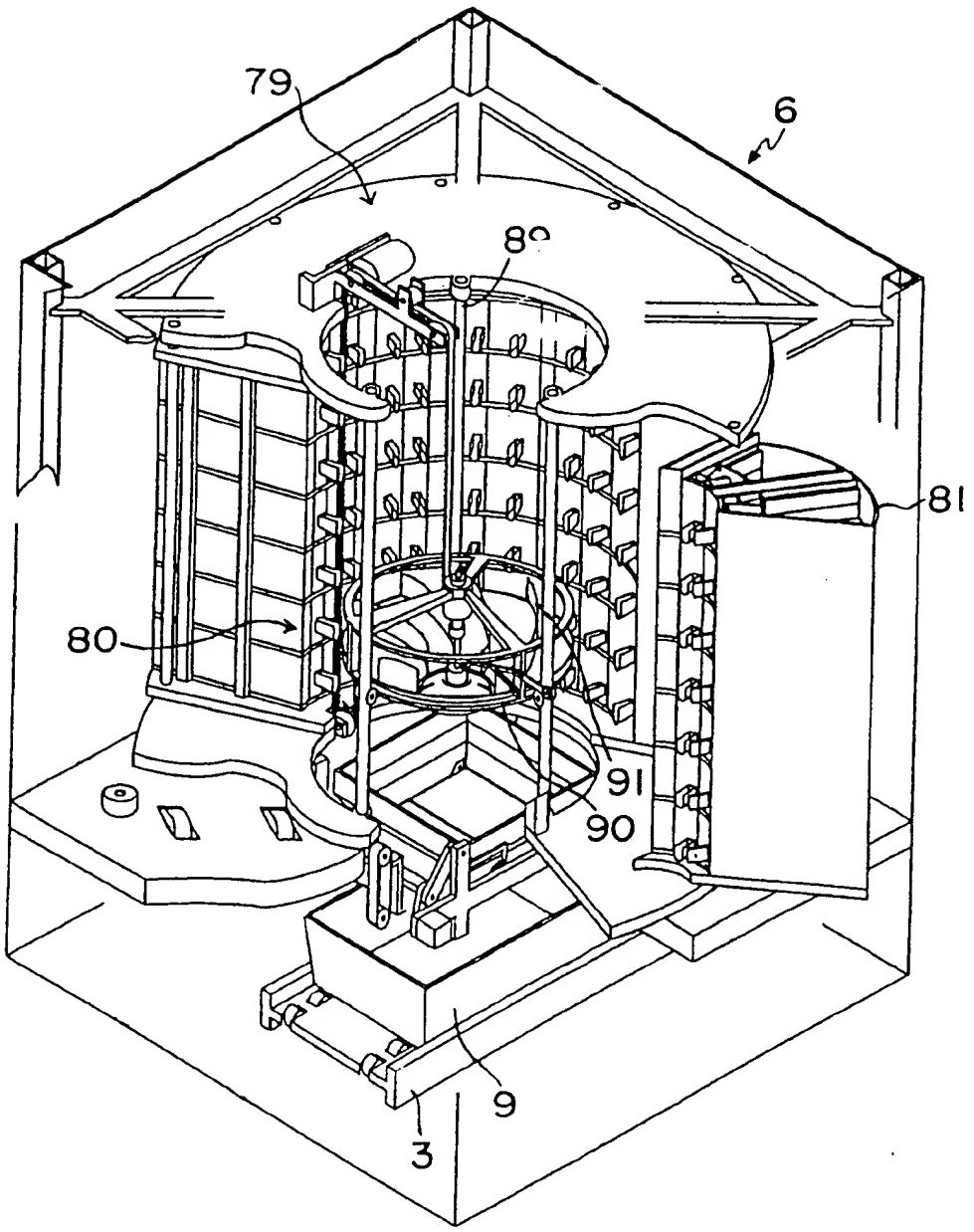

B
S10
Prompt the operator to enter the Manufacturer's Lot Number and Expiration from the bulk source.
S11
Present an alphanumeric keypad on the touchpanel for the operator to key in the values.
S12
Operator Keys in the Manufacturer's Lot and Expiration Dates and confirms by touching the appropriate button on the Touchpanel.
S13
Store the new Expiration Date and Lot Number in its database.
S14
Prompt the operator to scan the cassette location to verify correct return.
S15
Operator Scans the cassette location where the current cassette is missing. If wrong location is scanned, Touchpanel notifies the operator.
S16
Operator Replaces the Cassette into the location.
S17
Prompt the operator for the next cassette if this cassette is part of a cassette "grouping". (A grouping is a series of cassettes which contain the same drug and are automatically chosen if one becomes empty.)
S18
If Another Cassette, Repeat steps 5 through 17 for each cassette in the same grouping.
END

FIG. 21



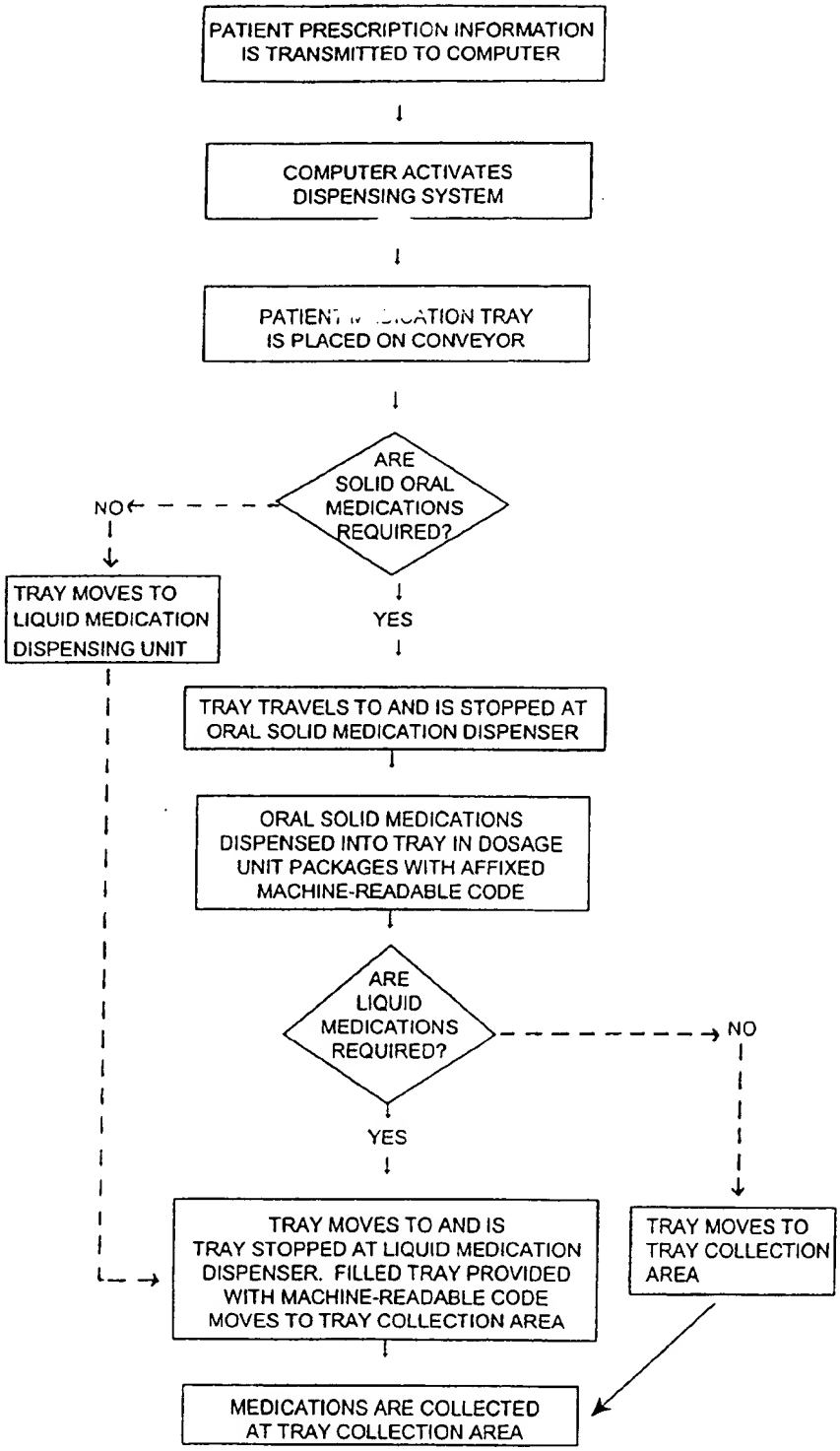

PATIENT PRESCRIPTION INFORMATION IS TRANSMITTED TO COMPUTER
COMPUTER ACTIVATES DISPENSING SYSTEM
PATIENT MEDICATION TRAY IS PLACED ON CONVEYOR
ARE SOLID ORAL MEDICATIONS REQUIRED?
NO
YES
TRAY MOVES TO LIQUID MEDICATION DISPENSING UNIT
TRAY TRAVELS TO AND IS STOPPED AT ORAL SOLID MEDICATION DISPENSER
ORAL SOLID MEDICATIONS DISPENSED INTO TRAY IN DOSAGE UNIT PACKAGES WITH AFFIXED MACHINE-READABLE CODE
ARE LIQUID MEDICATIONS REQUIRED?
NO
YES
TRAY MOVES TO AND IS TRAY STOPPED AT LIQUID MEDICATION DISPENSER. FILLED TRAY PROVIDED WITH MACHINE-READABLE CODE MOVES TO TRAY COLLECTION AREA
TRAY MOVES TO TRAY COLLECTION AREA
MEDICATIONS ARE COLLECTED AT TRAY COLLECTION AREA

Fig. 22

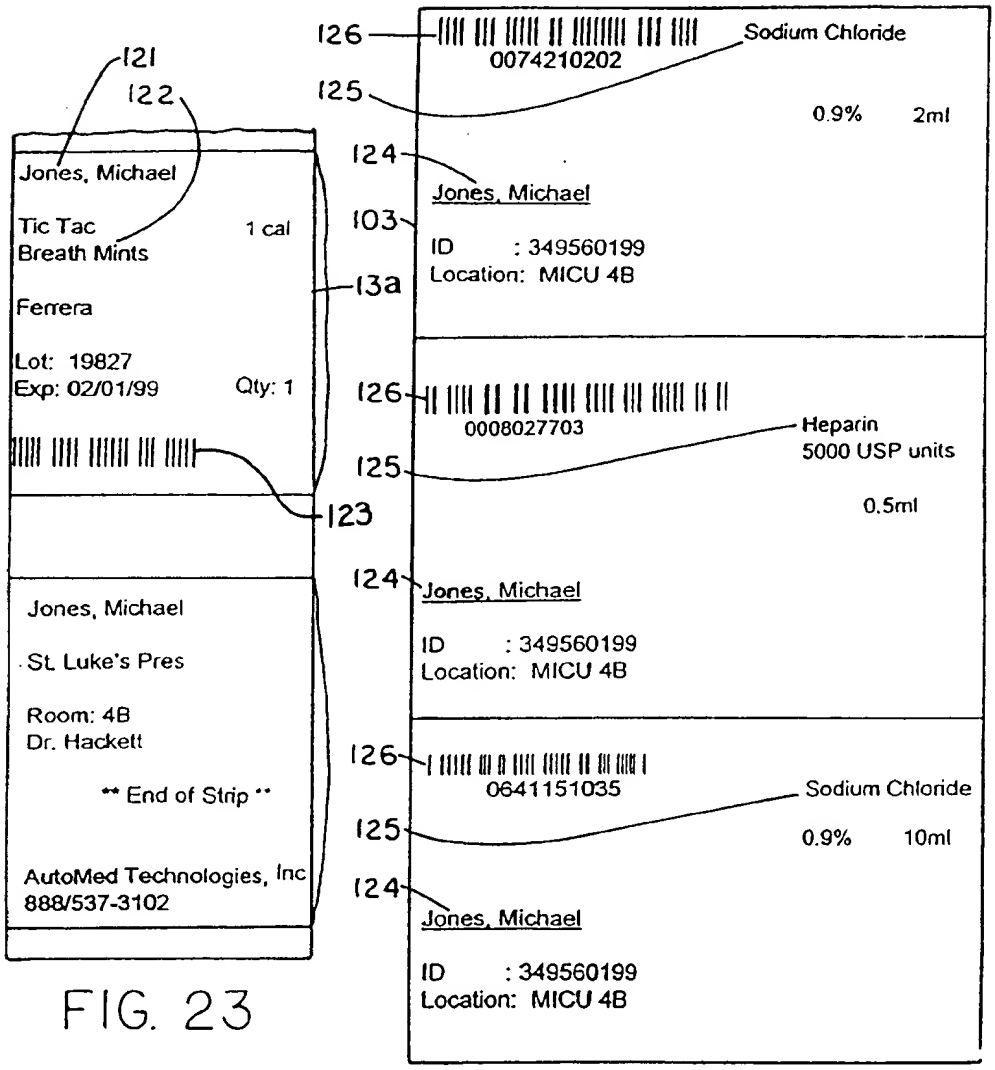

121
122
Jones, Michael
Tic Tac
Breath Mints
1 cal
Ferrera
Lot: 19827
Exp: 02/01/99
Qty: 1
123
Jones, Michael
St. Luke's Pres
Room: 4B
Dr. Hackett
** End of Strip **
AutoMed Technologies, Inc
888/537-3102
126
0074210202
Sodium Chloride
125
0.9% 2ml
124
Jones, Michael
103
ID : 349560199
Location: MICU 4B
13a
126
0008027703
Heparin
5000 USP units
125
0.5ml
124
Jones, Michael
ID : 349560199
Location: MICU 4B
126
0641151035
Sodium Chloride
125
0.9% 10ml
124
Jones, Michael
ID : 349560199
Location: MICU 4B

FIG. 23

FIG. 24

AutoFill System by AutoMed Technolgies Inc. Page 1 of 1

St. Luke's Presbyterian Hospital 101

Jones, Michael 127 11/08/1998 17:13 ID: 349560199

MICU 4B Fill For: 11/08/99

Order #: 128

Injectable Medications from AutoFill Checked By

Sodium Chloride 0.9% (0.308 milliosmois/mL) 2 ml
Quantity: 1
Give at [illegible] am

Heparin Sodium 5,000 USP 0.5 ml
Quantity: 1
Give at noon

131

Sodium Chloride 0.9% (0.308 milliosmois/mL) 10ml
Quantity: 1
Give at before bed

Oral Solid Medications from AutoFill Checked By

M&Ms packets: 3 (Quantity: 1 per Bag)
Give at 10:00 am, 4:00 pm and 10:00 pm

Skittles packets: 1 (Quantity: 2 per Bag)
Give at 10:00 am

131

TicTacs packets: 2 (Quantity: 1 per Bag)
Give at 10:00 am. 10:00 pm

Medications to be Manually Picked Checked By

None

Total: 6 med packets, 3 injectables, 0 Manual Items

FIG. 25

AUTOMATED METHOD FOR DISPENSING BULK MEDICATIONS WITH A MACHINE-READABLE CODE

FIELD OF THE INVENTION

This invention is related generally to automated dispensing technology and, more specifically, to an improved method for bulk dispensing of medication including information used to control and track patient medication orders.

BACKGROUND OF THE INVENTION

Automated dispensing of prescription medications, such as oral solid pills and liquid unit-of use ampules, is a well-known method of filling dosage-based prescriptions. Dosage-based prescriptions are filled in a way which organizes the medication into one or more dosage units by, for example, the time of day at which the medication is to be taken or the sequence in which the medication is to be taken. Dosage-based automated medication dispensing systems have particular utility in settings where large amounts of such prescription medications are required. Hospital formularies are ideal candidates for use of such dispensing systems. However, other businesses, such as mail order prescription filling services and pharmacies, can also use these systems.

Automated medication dispensing devices typically include one or more computer-controlled dispensing machines which store and dispense medications according to patient-specific prescription information. These automated medication dispensing devices offer many advantages. These advantages include the ability to store a broad range of prescription medications and the ability to fill patient prescriptions in a rapid and efficient manner. In addition, use of automated prescription filling equipment reduces the possibility of human error in filling patient prescriptions. Another advantage is that the cost savings from automated dispensing of medications can be used to employ more pharmacists and care givers who can provide personalized service to patients.

However, automated medication dispensing systems which attempt to dispense on a dosage unit basis have significant disadvantages. For example, certain dosage based systems are unable to fully utilize bulk medication dispensing technology. Bulk dispensing of medications involves the storage of pills or unit-of-use medications in bulk, for example in bins, magazines or canisters. The bulk-dispensed medications may be dispensed into containers according to patient-specific prescription information. As can be appreciated, bulk dispensing is most efficient when the medication is stored in a raw, non-prepackaged form since this permits great flexibility in the type of medications which can be dispensed and because the medications can be rapidly replenished in the bulk storage containers. Bulk dispensing becomes even more advantageous as the number and type of medications dispensed is expanded. For example, a hospital formulary is required to dispense dosage units of many different solid and liquid medications; an effective bulk dispensing system would be a particularly useful way to manage and control the distribution of such a diverse range of medications.

However, most prior art systems which provide dosage-based dispensing are required to store individual pills or medications in individual unit dosage packages and not in bulk. These separate unit dosage packages are stored within the dispensing device and must be separately retrieved to fill a patient's order. This is disadvantageous because it is difficult to arrange, customize and/or mix the pills comprising the patient's unit dosage. The process also requires time-consuming and expensive prepackaging of the medications to be dispensed. Such dosage-based systems are unable to realize the flexibility and cost savings benefits of bulk dispensing.

Another disadvantage of certain prior art dosage-based medication dispensing systems is that it is difficult to fully control and track the individual dosage units. The prepackaged dosage units used by these companies have preprinted information on the packages which is generic in nature and is not generated for the specific patient as the medication is dispensed. Such preprinted information might include National Drug Code ("NDC") information and a code for the storage location of the dosage unit within the dispensing. This information is limited and leaves little room for application of more patient-specific information such as the patient's name and other information which directly links the patient to the dosage unit. The Homerus system from Cardinal Health Care and the Robot Rx system from McKesson are representative dosage-based dispensers which include the foregoing disadvantages.

There are many potentially useful applications for the patient-specific information. For example, this information can be used at the completion of the filling process to verify that the correct medication has been supplied to the patient. The information could be used at the patient's bedside to create a record of the medication taken by the patient including the type and quantity of medication taken and the time of day at which the medication was taken. Patient-specific information on the medication packages could even be used for purposes of billing.

It would be a significant improvement in the art to provide an automated method for dispensing bulk medications in dosage form with real-time-generated machine-readable code so that the medication could be associated with a specific patient.

OBJECTS OF THE INVENTION

It is an object of this invention to provide an improved automated method of dispensing bulk medications overcoming problems and shortcomings of the prior art.

Another object of this invention is to provide an improved automated method of dispensing bulk medications with patient-specific machine-readable code affixed to the medication packaging.

It is also an object of this invention is to provide an improved automated method of dispensing bulk medications in which the machine-readable code affixed to the medication packaging can be used for many purposes including, without limitation, for verification that the order is correct and complete, for compliance with dosage protocols and for billing.

Another object of this invention is to provide an improved automated method of dispensing bulk medications in which patient-specific machine-readable code is affixed to the medication packaging in real time as the medication is dispensed.

A further object of this invention is to provide an improved automated method of dispensing bulk medications in which the prescriptions can be filled rapidly and economically.

Yet another object is to provide an improved automated method of dispensing bulk medications which avoids costly and time-consuming prepackaging steps.

An additional object of this invention is to provide an improved automated method of dispensing bulk medications which can be used with a wide range of medications including oral solid medications and unit-of-use liquid medications and other types of unit-of-use products.

How these and other objects are accomplished will be apparent from the descriptions of this invention which follow.

BRIEF DESCRIPTION OF THE DRAWINGS

The following description of an embodiment of the present invention is carried out with reference to the accompanying drawings, in which:

FIG. **1** is a schematic view of a medication collecting system according to an embodiment of the invention;

FIG. **2A** is a front view of an initial state showing the tray discharging structure of the tray feed station, and

FIG. **2B** is a front view in which the lowermost tray is discharged;

FIG. **3** is a partly broken perspective view showing the tablet dispensing station of FIG. **1**;

FIG. **4** is a front view showing the cutter part of the tablet dispensing station of FIG. **3**;

FIG. **5** is a perspective view showing the direction changing part of the tablet dispensing station of FIG. **3**;

FIG. **6** is a front sectional view showing the conveyor of the tablet dispensing station of FIG. **3**;

FIG. **7** is a perspective view showing the package-belt bundling section shown in FIG. **1**;

FIG. **8** is a perspective view showing the distributing member of the package-belt bundling section of FIG. **7**;

FIG. **9** is a side sectional view of the distributing member of the package-belt bundling section of FIG. **8**;

FIG. **10** is a partly broken perspective view showing the array ampule dispensing station of FIG. **1**;

FIG. **11A** is a front sectional view showing the ampule cassette of FIG. **10**,

FIG. **11B** is a partial sectional view showing an ampule discharging state including a stop provided in a lowermost portion of the ampule cassette, and

FIG. **11C** is a partial sectional view showing an ampule-holding state including the stop;

FIG. **12** is a partly broken perspective view showing the random ampule dispensing station;

FIG. **13A** is a front sectional view showing the ampule container of FIG. **12**, and

FIG. **13B** is a top sectional view showing the ampule container of FIG. **12**;

FIG. **14** is a sectional view showing the lifter part of FIG. **12**;

FIG. **15A** is a sectional view showing the lifter container of the lifter part of FIG. **14** with its bottom plates released from the closed state, and

FIG. **15B** is a sectional view showing a state in which the lifter container has been elevated from the position shown in FIG. **15A**;

FIG. **16** is a schematic perspective view showing the label issuing station of FIG. **1**;

FIG. **17** is a sectional view showing the tray recovering station of FIG. **1**;

FIGS. **18A** and **18B** are front views showing examples of the package belt in which medicaments are packed;

FIGS. **19A** and **19B** are flow charts showing the tablet replenishing work in the tablet dispensing station;

FIGS. **20A** and **20B** are flow charts showing the ampule replenishing work in the array ampule dispensing station or random ampule dispensing station;

FIG. **21** is a schematic sectional view of automatic packing station that can be provided instead of the tray recovering station of FIG. **17**;

FIG. **22** is a flow diagram of a preferred embodiment of the invention;

FIG. **23** is an example of an oral solid medication package including machine- readable code.

FIG. **24** is an example of machine-readable code labels for use with unit-of-use products such as liquid medications; and

FIG. **25** is an example of an instruction sheet which can be dispensed with the medication including dosage instructions and machine-readable code information.

SUMMARY OF THE INVENTION

The method provides an improved manner of dispensing bulk medications into dosage units together with machine-readable drug prescription information that can be used to control and track patient medication orders. The machine-readable code may be affixed to the medication packaging in real time as the medication is dispensed so as to directly link a dosage unit to a specific patient. The machine-readable code may be creatively configured to include any suitable information such as the patient name and dosage instructions. Use of bulk dispensing is fast, economical and permits the dosage units to be customized to the requirements of the patient both with respect to the type of medications and the ordering of the medications for consumption by the patient. The machine-readable patient information can be used for many purposes incident to the actual dispensing of the medication.

In general, the method comprises the initial step of providing at least one person's drug prescription information to a computer for controlling one or more bulk medication dispensing devices. The bulk dispensing device or devices used in the method automatically dispense and package a predetermined quantity of solid medication into at least one dosage unit in response to a signal from the computer based on the person's drug prescription information. The dispensing device or devices automatically apply machine-readable drug prescription information to the solid medication package in response to a signal from the computer based on the drug prescription information.

The dispensing apparatus used in the method can also automatically dispense a predetermined quantity of packaged liquid medication from a second bulk dispensing apparatus in response to a signal from the computer based on the person's drug prescript. information. The apparatus automatically provides machine-readable drug prescription information for application to the liquid medication package in response to a signal from the computer based on the drug prescription information. The packaged unit dosage packages are collected together with the machine-readable information so that the medication can be distributed to the person

Additional aspects of the method are explained in the detailed description which follows.

DETAILED DESCRIPTION

FIG. **1** shows a preferred embodiment of the apparatus used to perform many of the steps of the inventive method.

The apparatus is available from AutoMed Technologies, Inc. of Vernon Hills, Ill. and is sold commercially as the AutoFill System. One embodiment of such apparatus is descr... in U.S. patent application Ser. No. 09/205861, now U.S. Pat. No. 6,170,230 (Chudy et al.), the contents of which are incorporated herein by reference.

The exemplary medication dispensing system **200** shown in FIG. **1** includes a tablet dispensing station **4** an array ampule dispensing station **5**, a random ampule dispensing station **6** and a label issuing station **7**. These dispensers are disposed one after another along a conveyor line **3** that connects a tray feed station **1** and a tray recovering station **2** to each other.

These components are modular and can be configured and arranged to meet the needs of a specific operator. For example, additional tablet dispensing devices (such as tablet dispensing station **4**) could be added to the system **200** as could additional ampule dispensing stations (such as ampule dispensing stations **5** and **6**).

Conveyor line **3** need not be linear and can be configured to meet the space requirements of the particular operator.

Additional stations (not shown) can be added along the conveyor line. These stations might include automated unit-of-use dispensing devices for dispensing products such as intravenous solutions. In addition, stations consisting of pick-to-light storage shelf systems and non-automated storage shelf systems can be disposed along conveyor line **3** to provide an opportunity to place additional products and items into receptacles, shown as trays **9**.

We now turn to a more specific description of a preferred embodiment of the dispensing apparatus used to practice an example of the method.

Tray Feed Station

The tray feed station **1** is shown generally in FIG. **1**. A plurality of trays **9** are stored in tray feed station **1** in a stacked state within a cylindrical housing **8** having a rectangular cross section as shown in FIG. **2**A. Tray feed station **1** is enabled to feed out the trays **9** one by one. The housing **8** has, on its opposite sides, support feed claws **10** which are pivoted by an unshown motor or the like, respectively. The support feed claws **10** support peripheries of the lowermost tray **9** by their lower claw portions **10***a* and, by pivoting, place the lowermost tray **9** onto a feed-out plate **11** located below the lowermost tray **9**. During this process, the support feed claws **10** support peripheries of the next tray **9** by their upper claw portions **10***b* as shown in FIG. **2**B, thereby making it possible to take out only the lowermost tray **9**. In addition, the support feed claws **10**, after taking out the lowermost tray **9**, return to the original position and support the next tray **9** by their lower claw portions **10***a*. The feed-out plate **11**, which is guided by a lower opposite face of the housing **8**, can be moved up and down by a motor or the like. This feed-out plate **11** has a plurality of rotation-drivable rollers **12** provided in parallel. In the lower operating position, the feed-out plate **11** is enabled to transversely convey the tray **9** placed through a lower opening of the housing **8** and feed out the tray **9** to the conveyor line **3**.

Tablet Dispensing Station

The tablet dispensing station **4** shown in FIGS. **1** and **3** is provided to store bulk-form tablets **23** and to pack tablets **23** into a strip-shaped package belt **13** in doses. Tablet dispensing station **4**, comprises a tablet feed section **14**, a printing and packaging section **15** and a package-belt bundling section **16** (See FIG. **1**).

The tablet feed section **14** comprises a cylindrical drum **18** equipped with inner and outer tablet guide parts **17** which extend up and down. The tablet feed section **14** comprises a plurality of motor bases **19** disposed vertically and circumferentially on the outer periphery of each tablet guide part **17**, and a plurality of bulk storage tablet cassettes removably attached to the motor bases, respectively. Each tablet guide part **17** is divided circumferentially for each column of the vertically arrayed motor bases **19** and tablet cassettes **20**, by which a tablet guide passage **21** extending vertically is formed. Below the cylindrical drum **18**, are disposed hoppers **22***a*, **22***b*, which make it possible to collect tablets **23** dropping via the tablet guide passages **21** to one place.

In the tablet cassettes **20**, different types of tablets **23** are stored, respectively, and tablets **23** amounting to one-day doses are discharged in units of one dose based on prescription information. This arrangement permits the operator to bulk store and dispense a broad range of tablets **23**. The discharged tablets **23** are counted by sensors (not shown) provided on the motor bases **19**, and fed to the printing and packaging section **15** via the hoppers **22** through the tablet guide passages **21**. The number of tablets left in a tablet cassette **20** can be counted based on the initial number of pills stored and the count number by the sensor, allowing a decision as to whether or not the tablets **23** in cassette **20** have been depleted.

The printing and packaging section **15** comprises a roll **24** on which the package belt is wound, a printing part **25** for applying specified print on the surface of the package belt **13**, a sealing part **26** for sealing the package belt **13** in doses, and a cutter part **27** for cutting the package belt **13** into specified lengths.

The cutter part **27**, as shown in FIG. **4**, comprises a circular cutter **29** provided so as to be movable up and down along a guide shaft **28**, and a pivotal cutter guide **30** which has a guide recess for guiding the peripheral cutting edge of the cutter **29** and which is pivotal about a pivot **30***a* provided at an upper end. A rod **32** of a solenoid **31** is coupled to a lower end portion of the cutter guide **30** so that the cutter guide **30** can be put into adjacency to the package belt **13**, facilitating cutting by the cutter **29**.

The package-belt bundling section **16** is provided to bundle and bind the package belt **13** cut by the cutter **29**. To this package-belt bundling section **16**, the package belt **13** is fed via a direction changing part **33** and a conveyor **34**.

The direction changing part **33**, as shown in FIG. **5**, is provided to turn the cut package belt **13** approximately 90 degrees (from generally vertical to generally horizontal) while conveying the package belt **13** in a left to right direction in FIG. **5**. This direction changing part **33** comprises a guide member **35** for guiding the package belt **13**, a guide plate **36** for guiding the lower edge of the package belt **13** to the guide member **35**, and a wire **37** for gradually holding the upper edge of the package belt **13** to tilt package belt **13** sideways.

The conveyor **34**, as shown in FIG. **6**, is enabled to convey the package belt **13** obliquely upward by a horizontal conveyor belt **38** and a sloped conveyor belt **39**. A tension sheet **40** is disposed above part of the horizontal conveyor belt **38** and the sloped conveyor belt **39**. This tension sheet **40** is formed of a flexible material having small frictional resistance. A sponge roller **41** is pivotally-mounted on the entrance side of an insertion passage defined by the belt **38** and the tension sheet **40**. The belt **38** is set to a conveyance speed higher than that in the direction changing part **33**. If an unreasonable tensile force should act upon the package

belt **13**, an unshown limit switch is turned off by the swinging movement of the sponge roller **41** so that the driving of the belt **38** is stopped. Meanwhile, on the exit side of the insertion passage, a presser member **42** biased by a spring is provided, biasing the tension sheet **40** toward the belt **39**. As a result, the package belt **13** is pressed against the belt **38** with the frictional resistance increased, so that the package belt **13** can be prevented from clogging on the exit side. In addition, reference numeral **43** denotes a delivery belt to deliver package belt **13** to the package-belt bundling section **16**.

The package-belt bundling section **16**, as shown in FIGS. **7** and **8**, comprises an inverting member **44**, a lifter **45**, a feed-in member **46**, a bundling machine **47** and a distributing member **48**.

The inverting member **44** is supported so as to be reciprocally pivotal over a range of approximately 180 degrees about a support shaft **44a**. This inverting member **44** comprises a pull-in conveyor **49** for pulling in the package belt **13** from the delivery belt **43**. A stopper **50** for positioning the conveyed-in package belt **13** is protrusively provided at an end portion of the pull-in conveyor **49**. A sensor (not shown) is provided in proximity to the stopper **50** so that the presence or absence of the package belt **13** can be detected.

The lifter **45** is plate-shaped and has a side wall **45***a* extending along both side edge portions, and a recess **45***b* extending longitudinally in a central portion. The lifter **45** is reciprocally moved between a lower position where the package belt **13** is inverted by the inverting member **44** and can be loaded, and an upper position where the package belt **13** can be conveyed to the bundling machine **47** by the feed-in member **46**.

The feed-in member **46** has a brush **52** provided at an end of a feed-in arm **51** that reciprocally moves along the side portion **45***a* of the lifter **45** located in the upper position.

The bundling machine **47** comprises a looped rectangular frame body **53**, and a roller **55** on which bundling tape **54** is wound, where the central part of the stacked package belt **13** can be bundled with the tape **54** unwound from the roller **55**. A chute **56** is provided in proximity to the bundling machine **47** along which the package belt **13** is discharged. This chute **56** has a tip end directed obliquely upward prior to discharge of the package belt **13**. A presser **46***a* of the feed-in member **46**, presses a lever **56***a*, by which the chute **56** is pivoted and directed obliquely downward to discharge the package belt **13**.

The distributing member **48**, as shown in FIG. **8**, has an opening **58** formed in a sloped plate **57** directed obliquely downward, and this opening **58** is opened and closed by a distributing plate **59**. A lower end edge of the sloped plate **57** extends to the conveyor line **3**, allowing the bundled package belt **13** to be accommodated in the tray **9**. Also, a first link **60** is pivotally coupled at its one end portion to the distributing plate **59** as shown in FIG. **9**. A second link **62** provided on the rotating shaft of a motor **61** is pivotally coupled to the other end portion of the first link **60**. The motor **61** is so designed as to stop after every 180 degree rotation. As a result of this, the distributing plate **59** is pivotal between one position where the distributing plate **59** is aligned with the sloped plate **57** with the lower edge slightly out of alignment with the top surface, and another position where the distributing plate **59** is positioned generally vertical. Also, a dust box **63** is disposed below the opening **58** of the sloped plate **57**, so as to collect unnecessary portions (empty packages) of the package belt **13**.

Array Ampule Dispensing Station

The array ampule dispensing station **5**, as shown in FIG. **10**, comprises an ampule bulk storage section **64**, an ampule conveying section **65** and an ampule dispensing section **66**, and is used mainly to dispense ampules **67** each having a large capacity as much as 10 to 30 ml (for more details, see Japanese Patent Laid-Open Publication HEI 7-267370).

In the ampule storage section **64**, a plurality of drawer cradles **68** are provided in array. In each drawer cradle **68**, a plurality of ampule cassettes **69** are provided in array. Each ampule cassette **69**, as shown in FIG. **11**A, is shaped into a box having an openable/closable door **70** provided on one side face. Insidethe cassette **69**, the ampules **67** are stored in a laterally-postured and arrayed state. Also, as shown in FIGS. **1**B and **11**C, the lower face of the ampule cassette **69** is openedand a stop **71** is provided at the opening so as to prevent the ampules **67** from falling out. When the ampule cassette **69** is set up, only the lowermost-positioned ampule **67** can be discharged in a downward direction by withdrawing stop **71**. Further, handles **72**, each protruding in a generally L shape are formed above and below on one side face of the ampule cassette **69** perpendicular to the door **70**. A detent actuator portion **72***a* is formed in the lower handle **72**, so that an engaging detent **72***b* provided at the lower end surface of the ampule cassette **69** can be operated to extend and retract. By this engaging detent, the ampule cassette **69** can be attached to the drawer cradle **68**. The drawer cradle **68** is equipped with discharge rotors **73**, and the ampules **67** within the ampule cassette **69** can be discharged one by one by the discharge rotor **73** pivoting between the states of FIGS. **11**B and **11**A. In addition, an insertion hole (not shown) intended for a sensor is bored in the lower-end side surface of the ampule cassette **69**, making it possible to determine whether the remaining stock of ampules **67** has been decreased or has been depleted.

The ampule conveying section **65** comprises a first conveyor belt **74** disposed below the drawer cradle **68**, a stock storage **75** provided at the conveyance end of the first conveyor belt **74**, and a second conveyor belt **76** disposed below the stock storage **75** generally perpendicular to the first conveyor belt **74**.

The ampule dispensing section **66** comprises a stock container **77** for storing conveyed ampules **67**, and an up-down member **78** for discharging the ampules **67** stored in container **77** to the tray **9** on the conveyor line **3** while suppressing any impact force acting on the ampules **67**.

Random Ampule Dispensing Station

The random ampule dispensing station **6**, as shown in FIG. **12**, comprises a drum-shaped rotary storage rack **79**, and a lifter part **80** which goes up and down in the center of the rotary storage rack **79**, and is used to dispense mainly small-capacity ampules **81** (FIG. **13**) with a capacity less than 10 ml (for more details, see Japanese Patent Applications HEI 10-149489, HEI 10-99001, HEI 9-142473, HEI 9-212102, etc.)

In the rotary storage rack **79**, a plurality of ampule containers **82** are disposed vertically and circumferentially in so that an up-and-down space for the lifter part **80** **10** can be obtained on the central side. Each ampule container **82**, as shown in FIGS. **13**A and **13**B, comprises an ampule storage chamber **83** and an ampule array-and-conveyance section **84**. The ampules are bulk-stored within storage chamber **83** prior to dispensing. Different types of medications can be dispensed in the form of ampules **81** giving the operator flexibility in filling prescriptions.

A bottom wall **85** of the ampule storage chamber **83** is pivotal about a pivot **85***a*, and will be inclined by rotation of a rotating arm **86** so that the ampules **81** can be moved to the

ampule array-and-conveyance section **84**. Also, in the ampule array-and-conveyance section **84**, a belt **88** is stretched between pulleys **87** so that the ampules **81** placed on the belt **88** can be conveyed by one pulley **87** being rotated by the drive of a motor **87***a*. The ampule array-and-conveyance section **84** can be moved up and down by the drive of a motor, between a lower position where the ampules **81** within the ampule storage chamber **83** can be loaded on, and an upper position where the ampules **81** can be discharged to the lifter part **80** via a chute **83***a*. In addition, the ampule storage chamber **83** and the ampule array-and-conveyance section **84** are partitioned from each other by a shutter **83***b*, which is opened and closed with a pinion **83***c* and a rack **83***d*.

In the lifter part **80**, as shown in FIGS. **12** and **14**, a lifter container **90** is moved up and down along three rails **89** provided vertically in a center-side space of the rotary storage rack **79** (for more details, see Japanese Patent Application HEI 9-3071530) The lifter container **90** is funnel-shaped and has spiral guide blades **91** formed therein. The lifter container **90** is rotated by an unshown motor and guide blades **91** direct an ampule **67** to a central opening **92** under the guide by the guide blades **91**. The opening **92** is opened and closed by an opening/closing valve **94** that is moved up and down with an opening/closing arm **93**.

A delivery stock storage device **95** is provided below the lifter container **90**. As shown in FIG. **15**A, device **95** includes pivotally-mounted bottom plates **96**. Each bottom plate **96** is pivotal about a pivot **96***a* to form an opening **97** in the bottom of device **95** when in the position shown in FIG. **15**B. The bottom plates **96**, as shown in FIG. **14**, receive the ampules **6**–**7** from the lifter container **90**, and keep the bottom-face opening **97** closed by links **98** until the bottom plates **96** are located above and near the tray **9**. Then, when the bottom plates **96** are located above and near the tray **9**, the bottom plates **96** are released from the closed state by the links **98**, as shown in FIG. **15**A. As a result, when the lifter container **90** is moved up relative to the tray **9**, the bottom plates **96** pivot while keeping their free end portions in contact with the top face of the tray **9**, gradually opening the opening **97** as shown in FIG. **15**B. Accordingly, the ampules **67** discharged from the lifter container **90** are smoothly moved into the tray **9** without undergoing any impact force.

Label Issuing Station

The label issuing station **7** has a plurality of printers **99***a*, **99***b* arranged vertically as shown in FIG. **16**, and the uppermost three printers **99***a* are fed with prescription paper **101** from stock store **100**, respectively. This prescription paper **101** is provided so that a pharmacist may verify that the correct medication was dispensed. Also, the two printers **99***b* (shown juxtaposed below printers **99***a*) are each fed with labels, such as laber **103**, wound around a roll **102**. This label **103** is affixed to the ampules **67**, storage containers or the like, and is used to indicate their contents. Machine-readable information, such as bar code information, is printed on paper **101** and labels **103** as described elsewhere in the application.

Tray Recovering Station

In the tray recovering station **2**, as shown in FIG. **17**, a support base **106** is provided on rails **105** placed above and below in a support main frame **104** so that the support base **106** is reciprocally movable along an X-axis direction parallel to the conveyor line **3**. The support base **106** is equipped with guide rails **107** extending vertically. Base **108***a* movable up and down along guide rails **107** in a vertical Y-axis direction by a belt chain **108**. Base **108***a* is equipped with a cylinder **109**. Rod **109***a* of the cylinder **109** is equipped with a gripping arm **110**, which goes back and forth along a Z-axis direction perpendicular to the conveyor line **3**. The gripping arm **110** has at its front end a claw portion **10***a* formed for gripping a peripheral portion of the tray **9** (see also Japanese Patent Laid-Open Publication HE 9-51922 etc.).

System Operation

Next operation of the exemplary medication collecting system constructed as described above is explained.

When patient prescription information is read, a tray **9** is fed out from the tray feed station **1** to the conveyor line **3**. The tray **9** fed out to the conveyor line **3** is first conveyed to the tablet dispensing station **4**. If the patient's prescription information does not include tablets **23**, the tray **9** passes through the tablet dispensing station **4** without stopping. If tablet **23** information is included in the prescription, the tray **9** is stopped below the sloped plate **57** of the distributing m[illegible] **48**.

Tablet dispensing station **4** then dispenses tablets **23** in dosage units, such as one-day doses of medicaments. The tablets are fed from the relevant tablet cassette **20** in steps of one dose one after another according to the dosage time, and then are packed into medication packages formed in the package belt **13**.

As for the form of package, if a one-day dosage includes a plurality of times, for example, morning, noon and evening, then medication packages **13***a* of the tablets **23** are continuously packaged as shown in FIG. **18**A, or empty packages are formed between the medication packages **13***a* of the tablets **23** and the contents of the tablets **23**. Dosage information and the like are printed on these empty packages to make printed portions **13***b* as shown in FIG. **18**B. (Dosage information can also be printed on the packages containing tablets **23** as is the case in the package **13** shown in FIG. **23**.) In the former case, as shown in FIG. **18**A, the package belt is cut off by the cutter **29** with one-day doses taken as a unit. Thus, the need for bundling by the bundling machine **47** is eliminated. In the latter case, as shown in FIG. **18**B, the package belt is cut off by the cutter **29** with one dose taken as a unit. In addition, with a different patient, two empty packages **13***c* are additionally formed between a printed portion **13***b* for patient A and a medication package portion **13***a* for the next patient B, thus enabling continuous processing. Further, the empty packages **13***c* are separated from the other portions by the cutter **29**.

Subsequently, the cut package belt **13** is conveyed to the inverting member **44** via the direction changing part **33** and the conveyor **34**, so as to be transferred to the lifter **45**. For the package belt **13** or the empty packages **13***c* in the unit of one-day doses, the lifter **45** goes up without waiting for stacking by the transfer from the inverting member **44**; for the package belt **13** in the unit of one dose, the lifter **45** will not go up until the one-day doses have been completely stacked by the transfer from the inverting member **44**. Then, the cut package belt **13** is moved sideways by the feed-in member **46**, where in the case of the package belt **13** or empty packages **13***c* in the unit of one-day doses, the cut package belt **13** is passed through as it is without being bundled by the bundling machine **47**; in the case of the stacked package belt **13**, the cut package belt **13** is once stopped at the bundling machine **47**, where the cut package

belt **13** is bundled and then fed to the tray **9** via the distributing member **48**. In addition, in the distributing member **48**, for processing's sake, when empty packages **13***c* are conveyed up, the empty packages **13***c* are discarded to the dust box **63** via the opening **58** by rotating the distributing plate **59**.

Subsequently, the tray **9** is conveyed to the array ampule dispensing station **5**, and further to the random ampule dispensing station **6**. In this case also, based on the prescription information, the tray **9** is passed through as it is, or when ampules **67**, **81** are fed, the tray **9** is stopped at a relevant unit.

After that, the tray **9** is conveyed to the label issuing station **7**. In the label issuing station **7**, the prescription paper **101** on which prescription information as to all the medicaments within the conveyed-up tray **9** has been p[illegible] well as a label **103** to be affixed to the surface to sh[illegible] the contents of the stored ampules **67**, are fed into the tray **9**.

Now that desired medicaments have been fed to the tray **9** in this way, this tray **9** is conveyed to the tray recovering station **2**, where the medicaments are transferred onto shelves of a sorting cart (e.g., medication storage cabinet marketed by Pyxis Co.) C by the arm **110**. In addition, this sorting cart C is movably set in the nurse station, and put into use for distribution to the patients in hospital when the time to administer the medication has arrived.

Medication Replenishment Operation

Whereas the dispensing of medication is carried out as described above, the medication collecting system can detect the absence of any tablets **23** and ampules **67**, **81**, and can perform appropriate replenishment by checking these medicaments.

For this purpose, the tablet dispensing station **4** and the ampule dispensing stations **5**, **6** are equipped, although not shown, with a touch panel to be controlled by a controller, a wireless bar code reader with a recharging cradle therefor, and a scale.

In the tablet dispensing station **4**, the tablet cassettes **20** are exchanged according to the flow charts of FIGS. **19**A and **19**B. That is, when specified tablets **23** have come out of stock so that an empty tablet cassette **20** is detected (step S1) , the cylindrical drum **18** is rotated so that the empty tablet cassette **20** is moved to an interchangeable position, where its cassette number is notified, followed by a standby state (step S2). Also, a relevant medication profile is loaded from the database, and the current inventory count and expiration dates/lot numbers are displayed on the touch panel (step S3). Then, the operator obtains a wireless bar code scanner (step S4), reads the bar code of this tablet cassette **20**, verifying tablets **23** to be replenished (step S5) In this process, if the selected tablet cassette **20** is other than one containing the correct tablets **23**, the operator is informed of an error by the touch panel.

Subsequently, the operator places the empty tablet cassette **20** on the scale, where if the operator presses the "Tare" button on the touch panel (step S6), then the scale is initialized, prompting the operator to operate the bulk bottle for verification (step S7). If the verified bulk bottle is erroneous, the result is displayed on the touch panel, thereby notifying the operator of the error. If the verification result is correct, then the operator is prompted to pour in a desired quantity of medication into the scale. Then, if the operator has poured oral medication into the tablet cassette **20** on the scale (step S8), the scale counts the total medications poured into the tablet cassette **20** (step S9) In this case, if too much medication is poured in, a warning is presented on the touch panel.

Next, the operator operates a button on the touch panel, where if an end of the counting process is confirmed (step S10), then the final quantity is stored in the database (step S11). Subsequently, the operator is prompted to enter the manufacturer's lot number and expiration date according to the indication on the bulk bottle (step S12). Also, an alphanumeric keypad is displayed on the touch panel for the operator to key in values (step S13). If the operator has keyed in the manufacturer's lot number and expiration date and confirmed by touching an appropriate button on the touch panel (step S14), then the database is updated so that the lot number and expiration date are rewritten to the new ones (step S15).

After that, in order to verify a correct return place for the replaced tablet cassette **20**, the operator is prompted to scan the bar code of cassette location (step S16), and this is displayed on the touch panel. The operator sets a new tablet cassette according to this instruction, where the operator scans the bar code of the cassette location provided just above the motor base **19** with no tablet cassette **20** set. If a bar code of a wrong position is scanned, this fact is displayed on the touch panel so that the operator is notified of it (step S17). With these steps of work completed, the operator sets the tablet cassette **20** to the motor base **19** in the corresponding position, and returns the wireless scanner to the original position (step S18).

It is noted that, also for the ampule cassettes **69** and the ampule containers **82**, the processes described above are carried out similarly according to the flow charts shown in FIGS. **20**A and **20**B.

Consumables Management Operation

Also, in this medication collecting system, the consumption state of consumable articles (printing ink, package belt and the like) in the units can be detected.

For example, the remaining quantity of the package belt **13** which is used in the tablet dispensing station **4** is calculated based on an initial length and a length required per package. Similarly, the remaining quantity of the tape band **54** for the bundling machine **47** which is used in the tablet dispensing station **4** is calculated based on an initial length and a band feed quantity. Further, the remaining quantity of the prescription paper **101** which is used in the label issuing station **7** is calculated by subtracting the number of printed sheets from the initial setting number of sheets each time a printing process is performed. The remaining quantity of thermal transfer ink ribbon which is used in the label issuing station **7** is calculated based on an initial length and a consumption length (the consumption length for six-line printing is 3.5 mm).

Each time the consumption state of each consumable article is detected in this way, the consumable article data is updated and it is determined whether or not the article needs to be replaced. If it is decided that the article needs to be replaced, then an instruction that, for example, "Package paper will soon be out. Do you want to replenish?", and "YES/NO" keys are displayed on the display as a replenishment operating screen. If the "YES" key is chosen, then the replacement procedure for the relevant consumable article is displayed. Then, the article is replaced according to this procedure, and if the replacement is completed, a question, "Has replacement been completed?", and "YES/NO" keys are automatically displayed. If the "YES" key is chosen, the replenishment operating screen is ended and the consumable article data is updated, followed by a return to the normal screen.

Automatic Bagging Station

An automatic bagging station shown in FIG. 21 may be adopted instead of the tray recovering station 2 (for more details, see Japanese Patent Applications HE 10203749, HE 10-75813, etc.).

In this automatic bagging station, a sheet 112 wound around a roll 111 is formed into a bag shape by a sealing part 113 and cut into bags by a cutter 114, and the bags are printed on the surfaces by a printer 115 and then conveyed to a medication feed part 116. In the medication feed part 116, with the bags opened, medicaments within the tray 9 are all put into the bags, and after sealing, the bags are accommodated in a large-size tray 117 provided below the medication feed part 116. The large-size tray 117 is conveyed sideways by a conveyor 118.

Steps of the Preferred Method

Having described exemplary apparatus for practicing aspect of the invention and the operation of the apparatus we now turn to an example of the method. FIG. 22 is a flow chart which summarizes one form of the automated method for dispensing bulk medications with machine-readable code which may be practiced using the above-described dispensing apparatus.

According to a first step of the preferred method, at least one person's drug prescription information is provided to a computer 119 (not shown) for controlling the bulk medication dispensing system 200. Subsequently, a predetermined quantity of solid medication 23 is automatically dispensed and packaged into at least one dosage unit 13*a* from first bulk medication dispensing apparatus (tablet dispensing station 4) in response to a signal from computer 119 based on the person's drug prescription information. Machine-readable drug prescription information is automatically applied to the solid medication package 13*a* in response to a signal from computer 119 based on the drug prescription information.

A predetermined quantity of packaged liquid medication from a second bulk dispensing apparatus (such as ampule dispenser 5) is automatically dispensed in response to a signal from computer 119 based on one of the person's drug prescription information. Machine-readable drug prescription information 103 is automatically provided for application to the liquid medication package in response to a signal from the computer based on the drug prescription information. And, prescription paper 101 providing information about the entire filled prescription can also be provided. The medication packages including the machine-readable drug prescription information corresponding to the person's drug prescription are then collected.

While computer 119 initiates the filling sequence, it is contemplated that there may be intermediate steps or devices in the sequence by which the dispensing devices are controlled.

It is most preferred that the medications 23, 67, 81 be dispensed into a receptacle (such as tray 9) which is moved from dispenser to dispenser by conveyor 3 which is under the control of computer 119. Following dispensing, the tray 9 is moved by the conveyer 3 to tray collection station 1 where the patient-specific medication orders are collected for delivery to the patients.

The method may also be used to dispense dosage-based medications generally and without reference to a specific patient. Such medication may be used, for example in stocking a drug formulary.

It should be emphasized that the steps following the signal from the computer can be performed in any order and could occur simultaneously. For example, the tablet dispenser 4 and ampule dispenser 5 could be operating simultaneously, dispensing their medications when the tray 9 passes beneath the respective station. If medication from tablet dispenser 4 or ampule dispenser 5 is not required, the tray simply passes to the next station as shown in FIG. 22.

The invention may include a second computer 120 (not shown) at a site remote from computer 119 and may include entering at least one person's drug prescription information into second computer 120 and transmitting the drug prescription information from the second computer 120 to computer 119 for controlling the bulk medication dispensing apparatus 200. Computer 119 processes the information to control the bulk medication dispensing apparatus 200.

The method includes packaging of the solid medication 23 dispensed by tablet dispenser 4 in a continuous strip 13 and dividing the strip into at least one dosage unit such as 13*a*. As described above, machine-readable drug prescription information may be printed directly on the package. The machine-readable drug prescription information may alternatively be printed on a label applied to the package. FIG. 23 shows an exemplary package 13a with exemplary package information such as the patient's name 121, a description of the contents of the package 122 and a machine-readable bar code 123. Machine readable code 123 can include information customized to the operator's needs including patient name, doctor name, dosage instructions and other patient-specific information.

The method may further include the step of applying the machine-readable drug prescription information to a liquid medication package 67, 81 such as with the label information shown in FIG. 24. The information is preferably printed on perforated adhesive-backed paper 103 such as that shown in FIG. 24 and can simply be peeled off of the paper and applied to the liquid medication package 67, 81. FIG. 24 shows exemplary information such as the patient's name 124, a description of the contents of the package 125 and a machine-readable bar code 126 which can include information customized to the operator's needs including patient name, doctor name, dosage instructions and other patient-specific information.

As shown in FIG. 25, dosage instructions 101 including patient identification 127 information, human-readable dosage instructions 131 and machine-readable code 128 may be placed in tray 9 by printer 7. As in the case of the bar codes 123, 126 on the packages, the codes 128 on the instructions can include information tailored to the operator's request such as that described above. The machine-readable code need not be limited to bar codes and can include any suitable code.

The method can include further steps for utilizing the machine-readable code provided for the medication packages. Thus, for example, the method can include use of the information to verify that the correct unit dosage has been assigned to a patient. This can be accomplished by scanning the machine-readable code 123, 126 and/or 128 with any suitable scanner device 129 (not shown), transmitting the scanned code to the computer 119 and generating a signal from computer 119 to confirm that the packages correspond to the patient's drug prescription information.

Another use of the information is to verify that the correct medication is being given to the patient, for example, at the patient's bedside in a hospital. This could be performed by a nurse prior to the patient taking the medication. This

method comprises the further steps of scanning the machine-readable code **123**, **126** and/or **128**, transmitting the scanned code to the computer **119**, scanning machine-readable code **130** on the person's medical records (not shown), transmitting the scanned code to the computer **119** and generating a signal from computer **119** to confirm that the medication is suitable for the person. It is contemplated that the information scanned into computer **119** would be used for other purposes such as billing the patient or the patient's insurer for the medication.

While the principles of this invention have been described in connection with specific embodiments, it should be understood clearly that these descriptions are made only by way of example and are not intended to limit the scope of the invention.

What is claimed:

1. A method for dispensing bulk prescription medications into dosage units together with machine-readable drug prescription information comprising the steps of:

providing at least one person's drug prescription information to a computer for controlling bulk medication dispensing apparatus;

automatically dispensing and packaging a predetermined quantity of solid medication into at least one dosage unit from a first bulk medication dispensing apparatus in response to a signal from the computer based on the person's drug prescription information;

automatically applying machine-readable drug prescription information to the solid medication package in response to a signal from the computer based on the drug prescription information;

automatically dispensing a predetermined quantity of packaged liquid medication from a second bulk dispensing apparatus in response to a signal from the computer based on the person's drug prescription information;

automatically providing machine-readable drug prescription information for application to the liquid medication package in response to a signal from the computer based on the drug prescription information; and

collecting the medication packages including the machine-readable drug prescription information corresponding to the person's drug prescription.

2. The method of claim **1** further including a second computer at a site remote from the computer for controlling the bulk medication dispensing apparatus and comprising the further steps of:

entering at least one person's drug prescription information into the second computer; and

transmitting the drug prescription information from the second remote computer to the computer for controlling the bulk medication dispensing apparatus; whereby the computer for controlling the bulk medication dispensing computer uses the information to control the bulk medication dispensing apparatus.

3. The method of claim **1** wherein the solid medication packaging step includes packaging the solid medication in a continuous strip.

4. The method of claim **3** further including the step of dividing the strip into the at least one dosage unit.

5. The method of claim **1** wherein the step of applying machine-readable drug prescription information to the solid medication package comprises printing the information directly on the package.

6. The method of claim **5** wherein the machine-readable drug prescription information comprises a bar code.

7. The method of claim **1** further including the step of applying the machine-readable drug prescription information to the liquid medication package.

8. The method of claim **7** wherein the machine-readable drug prescription information comprises a bar code.

9. The method of claim **8** wherein the liquid medication is packaged in unit-of-use ampules.

10. The method of claim **1** wherein the method further comprises the steps of:

scanning the machine-readable code on the packages;

transmitting the scanned code to the computer; and

generating a signal from the computer to confirm that the packages correspond to the person's drug prescription information.

11. The method of claim **1** wherein the method further comprises the steps of:

scanning the machine-readable code on the packages;

transmitting the scanned code to the computer;

scanning machine-readable code on the person's medical records;

transmitting the scanned code to the computer; and

generating a signal from the computer to confirm that the medication is suitable for the person.

12. A method for dispensing bulk prescription medications together with machine-readable drug prescription information comprising the steps of:

providing at least one person's drug prescription information to a computer for controlling at least bulk medication dispensing apparatus and conveyor apparatus for transporting medication-holding receptacles to and from at least one bulk medication dispensing apparatus;

automatically dispensing and packaging at least one dosage unit of a predetermined quantity of solid medication from a first bulk medication dispensing apparatus containing a plurality of different medications in response to a signal from the computer based on the person's drug prescription information;

automatically applying machine-readable drug prescription information to the solid medication package in response to a signal from the computer based on the drug prescription information;

automatically dispensing the person's packaged, labeled solid medication into a receptacle on a conveyor;

automatically dispensing a predetermined quantity of packaged liquid medication from a second bulk dispensing apparatus in response to a signal from the computer based on the person's drug prescription information;

automatically providing machine-readable drug prescription information for application to the liquid medication packages in response to a signal from the computer based on the drug prescription information;

automatically dispensing the person's liquid medication and machine-readable drug prescription information into a receptacle on a conveyor; and

transporting the receptacle on the conveyor to a receptacle collection area.

13. The method of claim **12** further including a second computer at a site remote from the computer for controlling the bulk medication dispensing apparatus and comprising the further steps of:

entering at least one person's drug prescription information into the second computer; and

transmitting the drug prescription information from the second remote computer to the computer for controlling the bulk medication dispensing apparatus; whereby the computer for controlling the bulk medication dispensing apparatus computer uses the information to control the bulk medication dispensing apparatus and conveyor.

14. The method of claim **12** wherein the solid medication packaging step includes packaging the solid medication in a continuous strip.

15. The method of claim **14** further including the step of dividing the strip into the at least one dosage unit.

16. The method of claim **14** wherein the step of applying machine-readable drug prescription information to the solid medication package comprises printing the information directly on the package.

17. The method of claim **16** wherein the machine-readable drug prescription information comprises a bar code.

18. The method of claim **12** further including the step of applying the machine-readable drug prescription information to the liquid medication package.

19. The method of claim **12** wherein the method further comprises the steps of:

scanning the machine-readable code on the packages;

transmitting the scanned code to the computer; and

generating a signal from the computer to confirm that the packages correspond to the person's drug prescription information.

20. A method for dispensing bulk medications together with machine-readable drug prescription information identifying the medications comprising the steps of:

providing drug dispensing information to a computer for controlling bulk medication dispensing apparatus;

automatically dispensing and packaging in at least one dosage unit a predetermined quantity of solid medication from a first bulk medication dispensing apparatus in response to a signal from the computer based on the drug dispensing information;

automatically applying machine-readable drug identifying information to at least one solid medication package in response to a signal from the computer based on the drug dispensing information;

automatically dispensing a predetermined quantity of packaged liquid medication from a second bulk dispensing apparatus in response to a signal from the computer based on the drug dispensing information;

automatically providing machine-readable drug identifying information for application to the liquid medication package in response to a signal from the computer based on the drug dispensing information; and

collecting the medication packages including the machine-readable drug identifying information.

21. The method of claim **20** wherein the step of applying machine-readable drug prescription information to the solid medication package comprises printing the information directly on the package.

22. The method of claim **21** wherein the machine-readable drug prescription information comprises a bar code.

23. The method of claim **20** further including the step of applying the machine-readable drug prescription information to the liquid medication package.

24. The method of claim **23** wherein the machine-readable drug prescription information comprises a bar code.

25. A method for dispensing bulk prescription medications from at least a first bulk medication dispensing apparatus for dispensing solid medication and a second bulk medication dispensing apparatus for dispensing packaged liquid medication, said medications being dispensed into dosage units together with machine-readable drug prescription information, the method comprising the steps of:

providing at least one person's drug prescription information to a computer for controlling the bulk medication dispensing apparatus;

if the prescription information includes solid-medication information, automatically dispensing and packaging a predetermined quantity of the solid medication into at least one dosage unit from the first bulk medication dispensing apparatus in response to a signal from the computer based on the solid-medication information;

automatically applying machine-readable drug prescription information to the solid medication package in response to a signal from the computer based on the solid-medication information;

if the prescription information includes liquid-medication information, automatically dispensing a predetermined quantity of the packaged liquid medication from the second bulk dispensing apparatus in response to a signal from the computer based on the liquid-medication information;

automatically providing machine-readable drug prescription information for the packaged liquid medication in response to a signal from the computer based on the liquid-medication information; and

collecting the person's medication packages, including the machine-readable drug prescription information related thereto.

26. The method of claim **25** further including a second computer at a site remote from the computer for controlling the bulk medication dispensing apparatus and comprising the further steps of:

entering at least one person's drug prescription information into the second computer; and

transmitting the drug prescription information from the second computer to the computer for controlling the bulk medication dispensing apparatus;

whereby the computer for controlling the bulk medication dispensing apparatus uses the information to control the bulk medication dispensing apparatus.

27. The method of claim **26** wherein the solid medication packaging step includes packaging the solid medication in a continuous strip.

28. The method of claim **27** further including the step of dividing the strip into the at least one dosage unit.

29. The method of claim **27** wherein the step of applying machine-readable drug prescription information to the solid medication package comprises printing the information directly on the package.

30. The method of claim **25** wherein the machine-readable drug prescription information for application to the solid medication package comprises a bar code.

31. The method of claim **25** further including the step of applying the machine-readable drug prescription information to the liquid medication package.

32. The method of claim **25** wherein the machine-readable drug prescription information for application to the liquid medication package comprises a bar code.

33. The method of claim **25** wherein the liquid medication is packaged in unit-of-use ampules.

34. The method of claim 25 wherein the method further comprises the steps of:

scanning the machine-readable code on the packages;

transmitting the scanned code to the computer; and

generating a signal from the computer to confirm that the packages correspond to the person's drug prescription information.

35. The method of claim 25 wherein the method further comprises the steps of:

scanning the machine-readable code on the packages;

transmitting the scanned code to the computer;

scanning machine-readable code on the person's medical records;

transmitting the scanned code to the computer; and

generating a signal from the computer to confirm that the medication is suitable for the person.

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